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## In the Supreme Court of the United States

OCTOBER TERM, 1983

WILLIAM D. RUCKELSHAUS, ADMINISTRATOR, UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, APPELLANT

v.

#### MONSANTO COMPANY

ON APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF MISSOURI

#### JURISDICTIONAL STATEMENT

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#### QUESTIONS PRESENTED

1. Whether Section 3(c)(1)(D) of the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), 7 U.S.C. (& Supp. V) 136a(c)(1)(D) (which permits applicants to cite and EPA to consider in support of subsequent applications by other companies, health and safety data that were submitted to the government in support of initial applications for pesticide registration), works an unconstitutional taking of property requiring issuance of injunctive relief.

2. Whether 7 U.S.C. (Supp. V) 136a(c)(2)(A) and 7 U.S.C. (& Supp. V) 136h of FIFRA, which require EPA to disclose publicly health and safety data submitted to the agency in support of a pesticide registration application, are beyond Congress's power and constitute an unconstitutional taking of

property warranting injunctive relief.

3. Whether the constitutionality of the arbitration scheme established in 7 U.S.C. (Supp. V) 136a(c) (1) (D) (ii) (which provides that an original data submitter or an applicant who cited that data may initiate binding arbitration if the parties fail to agree on the amount of compensation) is ripe for review, and, if so, whether the arbitration provision denies due process or amounts to an unconstitutional delegation of judicial power.

## TABLE OF CONTENTS

	Page
Opinion below	1
Jurisdiction	1
Constitutional and statutory provisions involved	2
Statement	2
The questions presented are substantial	12
Conclusion	27
Appendix A	1a
Appendix B	39a
Appendix C	41a
Appendix D	44a
Appendix E	47a
TABLE OF AUTHORITIES Cases:	
Agins V. City of Tiburon, 447 U.S. 255	19
Almeida-Sanchez v. United States, 413 U.S. 266	16
Andrews v. Louisville & Nashville R.R., 406 U.S.	
320	25
Babbitt V. United Farm Workers National Union.	19, 22
442 U.S. 289	25
Berman v. Parker, 348 U.S. 26	- 15
Bowman Transp. v. ArkBest Freight System, 419 U.S. 281	14
U.S. 281	16
Chevron Chemical Co. v. Costle, 443 F. Supp. 1024	6
Chevron Chemical Co. v. Costle, 499 F. Supp. 732,	
aff'd on other grounds, 641 F.2d 104, cert. de-	
nied, 452 U.S. 961	17, 22
Country-Wide Insurance Co. v. Harnett, 426 F.	1
Supp. 1030, aff'd without opinion, 431 U.S. 934	25
Corn Products Refining Co. v. Eddy, 249 U.S. 427 Crane v. Hahlo, 258 U.S. 142	20
Orane V. Hano, 200 U.S. 142	24 - 25

Cases—Continued:	Page
Duke Power Co. v. Carolina Environmental	
Group, Inc., 438 U.S. 59	22
Edwards v. St. Louis-San Francisco R.R., 361	F.2d
FCC v. Schreider, 381 U.S. 279	20
Hancock v. Train, 426 U.S. 167	
Hardware Dealers Mutual Fire Insurance	Co. V.
Glidden Co., 284 U.S. 151	
Hodel v. Indiana, 452 U.S. 314	
Hodel v. Virginia Surface Mining & Reclam Ass'n, 452 U.S. 264	
Hurley V. Kincaid, 285 U.S. 95	24
Ludwig Honold Mfg. Co. v. Fletcher, 405 1123	F.2d 25
Mobay Chemical Corp. v. Costle, 12 E.R.C.	
appeal dismissed, 439 U.S. 320	5
Mobay Chemical Corp. v. Costle, 447 F. Supp.	
Mobay Chemical Corp. v. Costle, 517 F. Supp. aff'd, 682 F.2d 419, cert. denied, No. 8	. 252,
(Nov. 8, 1982)	200
Mulford v. Smith, 307 U.S. 38	14
National Fertilizer Ass'n v. Bradley, 301 U.S.	
Northern Pipeline Construction Co. v. Mar	
Pipe Line Co., No. 81-150 (June 28, 1982)	
Northern Securities Co. v. United States, 193	
197	14
Penn Central Transp. Co. v. New York City	
U.S. 104	17, 19
Pennsylvania Coal Co. v. Mahon, 260 U.S. 39	
Pennwalt Corp. v. Gorsuch, No. 80-2400 (W.I	
July 23, 1982)	13
Petrolite Corp. v. EPA, 519 F. Supp. 966	
PruneYard Shopping Center v. Robins, 447	
74	18
Regional Rail Reorganization Act Cases, 419	
102	22, 23, 24
Switchmen's Union v. National Mediation Bd	
U.S. 297	25
Union Carbide Agricultural Products Co. v. C	
632 F.2d 1014, cert. denied, 450 U.S. 996	

Cases—Continued:	Page
Union Carbide Agricultural Products Co. v. Ruckelshaus, No. 76 Civ. 2913 (RO) (S.D. N.Y. July	10
28, 1983)	13
United States v. Darby, 312 U.S. 100	14
Usery v. Turner Elkhorn Mining Co., 428 U.S. 1 Utah Fuel Co. v. National Bituminous Coal	12
Comm'n, 306 U.S. 56	20
Walker v. Southern Ry., 385 U.S. 196	25
Yearsley v. W.A. Ross Construction Co., 309 U.S. 18	23
Constitution, statutes and regulation:	
U.S. Const.:	
Amend. V2, 10, 13, 19, 22, 24, 2	5, 47a
Art. 1, § 8, Cl. 3 (Commerce Clause)10,	
Art. III	
Art. VI, Cl. 2 (Supremacy Clause)	17
Clean Air Act, 42 U.S.C. (Supp. V) 7607(a) (1) Federal Environmental Pesticide Control Act of	21
1972, Pub. L. No. 92-516, 86 Stat. 973 et seq	4
Section 3(c) (1) (D), 86 Stat. 979 Section 10, 86 Stat. 989	4, 5, 6
Federal Insecticide, Fungicide, and Rodenticide Act of 1947, 7 U.S.C. (1970 ed.) 135 et seq.: Section 3(c) (4), 7 U.S.C. (1970 ed.) 135a(c)	
(4)	4
Section 8(c), 7 U.S.C. (1970 ed.) 135f(c) Federal Insecticide, Fungicide, and Rodenticide	4
Act, 7 U.S.C. (& Supp.) 136 et seq	2
Section 2(bb), 7 U.S.C. 136(bb)	3
Section 3, 7 U.S.C. 136a	4
Section 3, 7 U.S.C. (& Supp. V) 136a9, 11,	13, 23
Section 3(b), 7 U.S.C. 136a(b)	9
Section 3(c) (1) (D), 7 U.S.C. (Supp. V) 136a	
(c) (1) (D)	passim
Section 3(c) (1) (D) (i), 7 U.S.C. (Supp. V)	
136a(c)(1)(D)(i)	7
Section 3(c) (1) (D) (ii), 7 U.S.C. (Supp. V)	
136a(c)(1)(D)(ii)7-8,	10, 26

Page	Constitution, statutes and regulation—Continued:
	Section 3(c) (1) (D) (iii), 7 U.S.C. (Supp. V)
8	136a(c)(1)(D)(iii)
10 11	Section 3(c) (2) (A), 7 U.S.C. (Supp. V) 136a
10, 11	(c) (2) (A)9,
	Section 3(c) (5), 7 U.S.C. (Supp. V) 136a(c)
3	(5)
	Section 3(c) (5) (C)-(D), 7 U.S.C. (Supp. V)
3	136a(c) (5) (C)-(D)
3	Section 3(c) (7), 7 U.S.C. (Supp. V) 136a(c)
9	(7)
	Section 6(d), 7 U.S.C. 136(d)
	Section 10, 7 U.S.C. (Supp. V) 136h
0 11	
8, 11	Section 10(d), 7 U.S.C. (Supp. V) 136h(d)
8	Section 10(d)(1), 7 U.S.C. (Supp. V) 136h
9, 21	(d) (1)
26	Section 10 (g), 7 U.S.C. (Supp. V) 136h (g) Section 30, 7 U.S.C. (Supp. V) 136x
20	
21	Federal Water Pollution Control Act, 33 U.S.C. 1319(b)
21	Safe Drinking Water Act, 42 U.S.C. 300j-4(d)
21	Toxic Substances Control Act, 15 U.S.C. 2613(b)
22	Tucker Act, 28 U.S.C. 1291
5	Pub. L. No. 94-140, 89 Stat. 751
22	15 U.S.C. 2217
5	28 U.S.C. 1253
21	42 U.S.C. 263g(d)
21	42 U.S.C. 5413(c) (5)
21	46 U.S.C. 1464 (d)
9	40 C.F.R. 164.31
	Miscellaneous:
9	123 Cong. Rec. 13097 (daily ed. July 29, 1977)
3	47 Fed. Reg. 53192-53221 (1982)
6, 9	H.R. Rep. No. 95-663, 95th Cong., 1st Sess. (1977)
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	Health and Safety Testing Information: Reform-
14	ing Agency Disclosure Policies, 93 Harv. L. Rev.
14	837 (1980)
10, 16	Restatement of Torts (1939)6

Miscellaneous—Continued:	Page
2 C. Sands, Sutherland Statutory Construction (4th ed. 1973)	26
Schulberg, The Proposed FIFRA Amendments of 1977: Untangling the Knot of Pesticide Regis-	
tration, 2 Harv. Envtl. L. Rev. 342 (1977)	6
S. Rep. No. 95-334, 95th Cong., 1st Sess. (1977)6	. 7. 15

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#### JURISDICTIONAL STATEMENT

#### OPINION BELOW

The opinion of the district court (App. A, infra, 1a-37a) is not reported.

#### JURISDICTION

The judgment of the district court (App. B, infra, 39a-40a) was entered on April 12, 1983. An amended judgment (App. C, infra, 41a-43a) was entered on May 9, 1983. The Administrator of the Environmental Protection Agency filed a notice of appeal to this Court on May 10, 1983 (App. D, infra, 44a-46a). On July 1, 1983, Justice Blackmun extended the time for docketing the appeal to August 8, 1983. The

jurisdiction of this Court is invoked under 28 U.S.C. 1252.

# CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

The Fifth Amendment to the United States Constitution and the relevant portions of the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. (& Supp. V) 136 et seq. are reprinted in App. E, infra, 47a-57a.

#### STATEMENT

1. This appeal involves a challenge to the constitutionality of key provisions of the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), 7 U.S.C. (& Supp. V) 136 et seq. These provisions govern the Environmental Protection Agency's ("EPA") use of health and safety information submitted to it by an applicant seeking to register a pesticide. The provisions at issue permit EPA to consider, in support of subsequent applications by other companies, health and safety data that were submitted to the government by the initial applicant (the "data consideration" provisions) and require EPA to disclose certain health and safety data to qualifying members of the public (the "data disclosure" provisions). Thus, the only data that are affected in this case relate to health and safety; the case does not involve product formulas or manufacturing processes, which are protected from disclosure by other statutory provisions.

Pursuant to FIFRA, pesticide manufacturers normally must obtain a registration from EPA before any pesticide product may be sold in the United States. A pesticide may be registered if its use will

When EPA registers a pesticide product under FIFRA, it approves the composition and labeling for that product and

not cause unreasonable adverse effects to the environment (7 U.S.C. (Supp. V) 136a(c)(5)), or, in the case of products similar to those already registered, will not significantly increase the risk of such effects (7 U.S.C. (Supp. V) 136a(c)(7)). EPA's decision whether to register a particular pesticide product depends upon its evaluation of both the usefulness of the product and the dangers presented by its use to human, animal, or plant life. See 7 U.S.C. 136(bb) and 7 U.S.C. (Supp. V) 136a(c)(5)(C)-(D). To carry out its regulatory responsibilities, EPA and its predecessors have required manufacturers to submit a variety of test data in support of applications for registrations. These data define the risks and benefits of the product for which registration is sought, and generally include data on the chemical nature and structure of the pesticide, as well as test data concerning the potential dangers of the product.2

allows that product to be sold for the approved labeling use. A label must contain: (1) general information such as the name of the manufacturer, and type of product and the registration number; (2) hazard statements; (3) directions for use; and (4) limitations on use (App. A, infra, 7a).

<sup>&</sup>lt;sup>2</sup> The health and safety data required for registration consist of the following major types of studies: (1) acute toxicity studies, which define how poisonous the pesticide is when ingested, inhaled, or applied to the skin or eyes; (2) chronic toxicity studies, which are used to determine if chronic exposure to the pesticide will have any long-term health effects such as causing cancer or birth defects; (3) residue studies, which define the level of the pesticide and its degradation products which remain in the food; (4) environmental chemistry studies, which are used to determine how much of the pesticide and its degradation products remain in the environment after application; and (5) fish and wildlife studies, which define how toxic the pesticide is to fish and wildlife which may be exposed to the pesticide after application in the environment (App. A. infra, 17a). See 47 Fed. Reg. 53192-53221 (1982).

As originally enacted in 1947, FIFRA was silent on the question of public disclosure of submitted health and safety data and on the authority to consider such data in support of subsequent applications for the same or similar pesticide by other companies.3 In 1972, Congress substantially revised FIFRA and for the first time addressed the issue of consideration and disclosure of submitted data. Federal Environmental Pesticide Control Act of 1972 (Pub. L. No. 92-516, 86 Stat. 973 et seq.) ("1972 Amendments"). A new Section 10 (86 Stat. 989) was added governing public disclosure of data submitted in support of applications for registration. This provision allowed applicants to designate portions of submitted data as "trade secrets or commercial or financial information" and it prohibited EPA from publicly disclosing any such information. In addition, Congress added a new Section 3(c)(1)(D) (86 Stat. 979) which provided that any "trade secret" data that could not be publicly disclosed under Section 10 could not be considered in support of another registration application, without the data-submitter's permission. All other data could be considered by EPA, but only if the later applicant offered the original data submitter compensation for

<sup>&</sup>quot;Under the original Act and until 1970, registrations were granted by the United States Department of Agriculture ("USDA"). In 1970, EPA assumed responsibility for registrations. 7 U.S.C. 136a. The Federal Insecticide, Fungicide, and Rodenticide Act of 1947 did not prohibit USDA from considering relevant data supplied to it by one applicant to support the applications of other companies, and USDA did not require applicants to duplicate tests already in USDA's files. The Act also contained no prohibition against public disclosure of data submitted in support of a registration (including health and safety data). It did, however, specifically prohibit disclosure of product formulas (7 U.S.C. (1970 ed.) 135a(c) (4) and 135f(c)).

its use. The amount of compensation would be determined either through negotiation between the parties, or would be fixed by EPA, subject to judicial review (*ibid.*).

The 1972 Amendments, however, failed to define "trade secrets," and failed to specify an effective date. The latter question was resolved in 1975 when Congress amended Section 3(c)(1)(D) to provide that the consideration provisions applied only to data submitted on or after January 1, 1970. Pub. L. No. 94-140, 89 Stat. 751. The definition of "trade secret" was left to the EPA Administrator and the courts.

EPA maintained that in the 1972 and 1975 Amendments Congress had intended to give trade secret protection to only a narrow range of data—principally statements of formulas and manufacturing processes. EPA thus concluded that the amendments did not protect health and safety data. Such data, therefore, could be disclosed to the public and could be considered by EPA in support of registration applications. In a series of lawsuits, data-submitting firms challenged EPA's interpretation and obtained several decisions holding that in 1972 Congress had intended the "trade secret" prohibition to apply to any data, including health and safety data, that met the expansive "trade secret" criteria specified in the

<sup>\*</sup>Section 3(c) (1) (D), as amended in 1975, was challenged by an original data submitter on the ground that Section 3(c) (1) (D) caused an unconstitutional taking of its property rights in the data it had submitted prior to January 1, 1970. This claim was rejected by a three-judge court, which held that Section 3(c) (1) (D) did not "take" any property rights. Mobay Chemical Corp. v. Costle, 12 E.R.C. 1572 (W.D. Mo. 1978). A direct appeal to this Court under 28 U.S.C. 1253 was dismissed on the ground that the three-judge court had been improperly convened. 439 U.S. 320 (1979).

Restatement of Torts § 757 (1939). E.g., Chevron Chemical Co. v. Costle, 443 F. Supp. 1024 (N.D. Cal. 1978); Mobay Chemical Corp. v. Costle, 447 F. Supp. 811 (W.D. Mo. 1978). As a result of these decisions, the "trade secret" prohibition in Section 10 operated to bar public access to much of the data on which EPA based its decisions to register pesticides; and the corresponding prohibition in Section 3(c) (1) (D) allowed data-submitters to prevent any other firm from obtaining registrations for products that were the same or substantially the same as previously registered products unless the second firm duplicated the data supporting the first registration or it was determined, after perhaps years of litigation, that particular items of data were not trade secrets. In part because of such "trade secret" controversies, "the process of registering new pesticides simply ground to a halt." Chevron Chemical Co. v. Costle, 499 F. Supp. 732 (D. Del. 1980), aff'd on other grounds, 641 F.2d 104, 111 (3d Cir.), cert. denied, 452 U.S. 961 (1981). See H.R. Rep. No. 95-663, 95th Cong., 1st Sess. 18 (1977), S. Rep. No. 95-334, 95th Cong., 1st Sess. 3 (1977).

Faced with this breakdown in the registration program, Congress, in the Federal Pesticide Act of 1978 ("1978 Amendments"), comprehensively revised the FIFRA data consideration and disclosure provisions, changing both Sections 3(c)(1)(D) and 10. The 1978 Amendments abolished the earlier prohibition (in Section 3(c)(1)(D)) on agency consideration of "trade secret" data because it had operated to discourage small potential competitors from entering the market by requiring them to duplicate health and safety tests for products already established as

<sup>&</sup>lt;sup>5</sup> See generally Schulberg, The Proposed FIFRA Amendments of 1977: Untangling the Knot of Pesticide Registration, 2 Harv. Envtl. L. Rev. 342 (1977).

registrable by data that were contained in EPA's files but were rendered inaccessible by statute.6 Congress was concerned that the FIFRA data requirements, in practice, acted as a de facto extension of patents beyond the statutory period of protection. See, e.g., S. Rep. No. 95-334, 95th Cong., 1st Sess. 8, 30-31 (1977). In order to encourage competition and eliminate needless duplicative testing on pesticide chemicals already determined to be safe (see S. Rep. No. 95-334, supra, at 30, 31), Congress established a new and comprehensive registration scheme. The new scheme spreads the costs of developing health and safety data among all beneficiaries of the data while at the same time protecting innovation incentives through exclusive use and compensation provisions (ibid.). Under the 1978 Amendments, applicants are granted a 10-year period of exclusive use for data on new active ingredients contained in pesticides registered after September 30, 1978. Section 3(c)(1)(D) (i), 7 U.S.C. (Supp. V) 136a(c) (1) (D) (i). All other data submitted after December 31, 1969, may be cited and considered in support of another application for 15 years following the original submission, if the applicant offers to compensate the original submitter. Section 3(c)(1)(D)(ii), 7 U.S.C. (Supp. V) 136a (c) (1) (D) (ii). In these instances, the data are not

<sup>&</sup>lt;sup>6</sup> Most of the pesticide products for which registration is sought contain active ingredients that are also contained in previously registered products. Because the first registrant(s) of products containing a particular active ingredient normally will have supplied substantial amounts of health and safety data, EPA's files contain much data relevant to subsequent decisions whether to register other products containing the same ingredient. As the district court found, most of the testing and research is done by a few, relatively large firms, of which Monsanto is one (App. A, infra, 4a).

disclosed to the later applicant but are viewed only by EPA personnel. The later applicant, in order to cite the data, must offer to compensate the original submitter; if the parties cannot agree on the amount of compensation, either may initiate binding arbitration proceedings. Data that do not qualify for either the 10-year period of exclusive use or the 15-year period of compensation may be considered by EPA without limitation. Section 3(c)(1)(D)(iii), 7 U.S.C. (Supp. V) 136a(c)(1)(D)(iii).

The 1978 Amendments also added a new provision, Section 10(d) (7 U.S.C. (Supp. V) 136h(d)), that provides for public disclosure of all health and safety data.\* This provision was designed to enable members of the public to assess for themselves the hazards posed by pesticide products and to participate in and evaluate EPA's registration decisions. See, e.g., H.R.

<sup>&</sup>lt;sup>7</sup> The decision of the arbitrator may be overturned for "fraud, misrepresentation, or other misconduct." 7 U.S.C. (Supp. V) 136a(c) (1) (D) (ii).

<sup>&</sup>lt;sup>8</sup> Under Section 10(d) (1), 7 U.S.C. (Supp. V) 136h(d) (1), EPA must, on request, disclose to qualified requestors "[a]ll information concerning the objectives, methodology, results, or significance of any test or experiment performed on or with a registered or previously registered pesticide or its separate ingredients, impurities, or degradation products, and any information concerning the effects of such pesticide on any organism or the behavior of such pesticide in the environment, including, but not limited to, data on safety to fish and wildlife, humans and other mammals, plants, animals, and soil, and studies on persistence, translocation, and fate in the environment, and metabolism."

Because of the health and safety significance of the data submitted in support of an application for a pesticide registration, EPA often receives requests for access to this infor-

Rep. No. 95-663, 95th Cong., 1st Sess. 18 (1977); 123 Cong. Rec. 13097 (daily ed. July 29, 1977) (remarks of Sen. Kennedy). The same section, however, prohibits EPA from disclosing information that would reveal "manufacturing or quality control processes" or certain details pertaining to "deliberately added" inert ingredients unless "the Administrator has first determined that disclosure is necessary to protect against an unreasonable risk of injury to health or the environment." In addition, Section 10(g) generally prohibits EPA from disclosing data to foreign or multinational pesticide producers, unless the original submitter consents. Section 10(g), 7 U.S.C. (Supp. V) 136h(g).

2. In its complaint in the United States District Court for the Eastern District of Missouri, Monsanto sought injunctive and declaratory relief from the operation of the data consideration provisions of Section 3(c)(1)(D), 7 U.S.C. (Supp. V) 136a(c)(1)(D), and the disclosure provisions of Section 10, 7 U.S.C. (Supp. V) 136h and related Section 3(c)(2)(A), 7 U.S.C. (Supp. V) 136a(c)(2)(A). Monsanto alleged

mation from environmental organizations interested in protecting man and the environment from the adverse effects of these pesticide chemicals, from farm worker unions that serve to protect the interest of farmworkers who are directly exposed to the pesticides used in the fields where they work, and from union groups that represent the chemical workers who manufacture pesticides. Moreover, FIFRA specifically provides for public participation in EPA's decision-making process. Members of the public may petition EPA to take regulatory action. See 7 U.S.C. (& Supp. V) 136a. They may comment in rule-making proceedings and on other regulatory actions. See, e.g., 7 U.S.C. 136a(b). And, they may petition for the commencement of, and participate in, administrative hearings to cancel or deny a pesticide registration. See, e.g., 7 U.S.C. 136d(d); 40 C.F.R. 164.31.

that (1) the data consideration provision, Section 3(c)(1)(D), constitutes a "taking" of property for a private purpose without just compensation, in violation of the Fifth Amendment and (2) the data disclosure provisions, Sections 3(c)(2)(A) and 10, are beyond Congress' Commerce Clause powers and effectuate a taking without just compensation in violation of the Fifth Amendment. Monsanto further contended that the compulsory and binding arbitration scheme provided in Section 3(c)(1)(D)(ii) violates the company's due process rights and constitutes an

unconstitutional delegation of judicial power.

Following a bench trial, the district court ruled in favor of Monsanto. The court concluded that the data consideration and disclosure provisions of FIFRA are beyond Congress' Commerce Clause powers and constitute an unconstitutional taking of property in violation of the Fifth Amendment. The court held that Monsanto has a state-protected property right (based on the trade secret definition in the Restatement of Torts § 757 (1939)) in the data it submits to EPA. which precludes EPA from considering Monsanto's data in support of another person's registration application or from disclosing the data publicly. Section 3(c)(1)(D), the court concluded, appropriates Monsanto's "fundamental right \* \* \* to exclude" others from use of its property, furthers private rather than public purposes, and operates as an unconstitutional taking of Monsanto's property (App. A, infra, 31a-32a). The Court also found that FIFRA's disclosure provisions (Sections 3(c)(2)(A) and 10) "effectively destroy" Monsanto's property, adding that disclosure is "beyond Congress' regulatory powers" because the public interest is satisfied by EPA's analysis of the pesticide's safety and by the labeling requirements

under FIFRA (App. A, infra, 32a-33a). The court further concluded that Congress had withdrawn the Tucker Act remedy to provide Monsanto with "just compensation," on the ground that the compensation and exclusive use provisions of Section 3 (7 U.S.C. (& Supp. V) 136a) "were intended to be the sole compensation for any taking" (App. A, infra, 35a). Finally, the court held that the data-compensation scheme established in Section 3 is unconstitutional because it does not provide "just compensation" and because it denies Monsanto "due process" and amounts to an unconstitutional delegation of judicial power (App. A, infra, 34a). The court recognized that every other court which had considered these issues had held FIFRA constitutional (see page 13, infra) but chose not to follow those decisions (App. A, infra, 36a-37a).

The district court enjoined EPA from implementing "in any manner, directly or indirectly," FIFRA Sections 3(c)(1)(D) and (2)(A), 10(b) and (d) (App. A, infra, 40a). In addition, it specifically enjoined "any use or consideration of or disclosure to any other person of any of Monsanto's information. research and test data, whenever submitted unless [EPA] shall have first obtained Monsanto's express written permission" (ibid.). Both EPA and Monsanto moved to amend the judgment. EPA sought to clarify that the judgment did not preclude release of Monsanto's health and safety data to other agencies of the federal government or to Congress. EPA also moved for a stay pending appeal to this Court. Monsanto asked the court to add a new paragraph to the judgment specifying that EPA could process registrations for those manufacturers that can generate their own data or obtain the data from another manufacturer. On May 9, 1983, the district court issued an amended judgment that accommodated both EPA's

and Monsanto's requests for amendment, but denied EPA's motion for a stay (App. B, infra, 39a-40a). On July 1, 1983, EPA moved in this Court for a stay pending appeal. On July 27, 1983, the stay was denied. Ruckelshaus v. Monsanto Co., No. A-1066 (Blackmun, Circuit Justice).

### THE QUESTIONS PRESENTED ARE SUBSTANTIAL

The district court has declared unconstitutional several key provisions of FIFRA that effectuate Congress' express intent that the pesticide registration program be made more efficient, that competition in the industry be increased, and that the potential hazards of pesticide products be disclosed to the public. The comprehensive scheme created by Congress reflects a careful balance between the need for increased competition and the need for innovation in the pesticide industry. The scheme also accommodates private industry's interest in protecting information and the public's interest in understanding the potential risks and dangers of pesticide products. If the decision below is allowed to stand, numerous safe and effective pesticides (including new uses for pesticides) will not be registered and the public will be deprived of vital information necessary to evaluate properly a pesticide's hazards and EPA's registration decisions.

The district court decision is erroneous for several reasons. First, the court all but ignored the well-established principle that "legislative Acts adjusting the burdens and benefits of economic life come to the Court with a presumption of constitutionality \* \* \*." Usery v. Turner Elkhorn Mining Co., 428 U.S. 1, 15 (1976). Second, the decision totally disregards Congress' findings concerning the need for more competition in the pesticide industry, greater efficiency in

the registration program, and public disclosure. The decision is also inconsistent with the decisions of this Court construing the Commerce Clause and the Fifth Amendment, and conflicts with the prior judicial decisions involving similar challenges to the same statutory provisions. Prior to the decision below, all courts that had ruled on the constitutionality of the data consideration and disclosure provisions had upheld them as a rational means for effectuating Congress' intent. See Mobay Chemical Corp. v. Costle, 517 F. Supp. 252 (W.D. Pa. 1981), aff'd, 682 F.2d 419 (3d Cir.), cert. denied, No. 82-241 (Nov. 8, 1982); Pennwalt Corp. v. Gorsuch, No. 80-2400 (W.D. Pa. July 23, 1982), aff'd as a companion case in Mobay, supra; Chevron Chemical Co. v. Costle, 499 F. Supp. 732 (D. Del. 1980), aff'd on other grounds. 641 F.2d 104 (3d Cir.), cert. denied, 452 U.S. 961 (1981); Petrolite Corp. v. EPA, 519 F. Supp. 966 (D.D.C. 1981). See also Union Carbide Agricultural Products Co. v. Costle, 632 F.2d 1014 (2d Cir. 1980). cert. denied, 450 U.S. 996 (1981) (refusing to preliminarily enjoin operation of Sections 3(c)(1)(D) and 10 pending resolution of Union Carbide's constitutional challenge).10 This Court should note probable jurisdiction to review the district court's dubious constitutional rulings, to confirm the validity of Congress' careful scheme to regulate the pesticide indus-

<sup>&</sup>lt;sup>10</sup> Subsequent to the decision in the present case, the district court in *Union Carbide* upheld the constitutionality of Section 10 and found the arbitration scheme to be an unconstitutional delegation of judicial authority. It did not otherwise rule on the data consideration provisions of Section 3 and has not yet entered a remedial order. *Union Carbide Agricultural Products Co. v. Ruckelshaus*, No. 76 Civ. 2913(RO) (S.D.N.Y. July 28, 1983).

try in the public interest, and to resolve the conflicting decisions of the lower courts.

1. Congress clearly has the power under the Commerce Clause to regulate the pesticide industry in a manner that promotes the public health and welfare. Congress may properly act "to prevent the flow of commerce from working harm to the people of the nation," Mulford v. Smith, 307 U.S. 38, 48 (1939), and may enact broad provisions to aid the accomplishment of these goals. See, e.g., United States v. Darby, 312 U.S. 100, 121 (1941). Courts have consistently found the commerce power broad enough to permit congressional regulation of activities causing potential environmental hazards. Hodel v. Virginia Surface Mining & Reclamation Ass'n, 452 U.S. 264, 282 (1981). In addition, regulation of competition is a long-established and well-developed power of Congress under the Commerce Clause. Bowman Transp. v. Ark.-Best Freight System, 419 U.S. 281, 298 (1974): Northern Securities Co. v. United States, 193 U.S. 197, 337-338 (1904). The challenged provisions of FIFRA are a rational means for effectuating Congress' intent.

Section 10 rationally effectuates Congress' interest in minimizing the hazards of pesticide use. Disclosure enables members of the public to assess for themselves the safety and efficacy of pesticide products, many of which are inherently dangerous. Disclosure also enables members of the public to participate in and evaluate EPA's pesticide registration decisions.<sup>11</sup> The district court's conclusion that "the court cannot

<sup>&</sup>lt;sup>11</sup> See generally McGarity & Shapiro, The Trade Secret Status of Health and Safety Testing Information: Reforming Agency Disclosure Policies, 93 Harv. L. Rev. 837 (1980).

fairly say that Section 10's public disclosure provisions are a regulation of commerce" (App. A, infra, 33a) is patently incorrect, particularly in light of the

Constitution's "necessary and proper clause."

Section 3(c)(1)(D) also rationally effectuates Congress' desire to increase competition in the pesticide industry and to promote an efficient registration program. By removing needless barriers to market entry created by the data submission requirements of FIFRA, Section 3(c)(1)(D) promotes Congress' desire to advance competition. In addition, by reducing the burden of duplicating test data and spreading the cost of testing equitably throughout the industry, by means of the exclusive use and data compensation scheme, Section 3(c)(1)(D) enhances the efficient operation of the registration system. In holding that there is adequate competition in the pesticide industry and that the section therefore "unabashedly operates to further a private purpose" (App. A, infra, 32a), the district court improperly intruded upon the legislative domain. The legislative history fully supports Congress' determination that there is a need for more competition in the pesticide industry. See, e.g., S. Rep. No. 95-334, supra, at 3, 8, 31. Accordingly, the court was not free to substitute its judgment for Congress' finding of public need. Hodel v. Indiana, 452 U.S. 314, 326 (1981). Moreover, because the Act serves a valid public purpose, the fact that private persons may also derive benefit is irrelevant. Berman v. Parker, 348 U.S. 26, 32 (1954).

2. The district court's conclusion that Sections 3(c) (1)(D) and 10 of FIFRA constitute a taking of Monsanto's property without just compensation is also erroneous. These sections deal only with health and safety data. Thus, subsequent applicants relying on Section 3(c)(1)(D) to obtain a registration must

still provide the agency with their own formulas and manufacturing processes. Section 10 prevents the disclosure of formulas and manufacturing processes in most instances. The district court correctly recognized that there is nothing in federal law that precludes the government from using the health and safety data voluntarily submitted by Monsanto to further the government's regulatory responsibilities (App. A, infra, 29a). The court determined, however, that Monsanto has a state-protected right based on the Restatement of Torts § 757 (1939) (App. A, infra, 29a), which precludes government use. 12

We do not dispute that while the data remained exclusively in Montsanto's hands any trade secrets contained in the data were protected by state law. Monsanto could have preserved any trade secret in its health and safety data by forgoing the opportunity to seek a registration. It could have decided to sell or license the health and safety data to others. Monsanto, however, chose to disclose that data to EPA in exchange for commercially valuable pesticide registrations. Once Monsanto made the decision to obtain a valuable registration, the company accepted the conditions for obtaining the registration. Cf. Almeida-Sanchez v. United States, 413 U.S. 266, 271 (1973) ("The businessman in a regulated industry in effect consents to the restrictions placed upon him."). It

<sup>12</sup> Significantly, under Missouri law a trade secret does not last into perpetuity. Missouri has adopted the "head start" rule which provides that a trade secret lasts for only "'[t] hat period of time which would have been required by defendants to reproduce plaintiff's products without wrongful appropriation.'" Carboline Co. v. Jarboe, 454 S.W.2d 540, 552-553 (Mo. 1970). The exclusive use period mechanism adopted in FIFRA is essentially a "head start" rule, and thus provides Monsanto with the same and perhaps even greater protection than it is entitled to under state law.

follows that Monsanto does not retain any state law right that interferes with Congress' authority to direct EPA to make internal use of data submitted to it or to disclose to the public health and safety data relevant to potential hazards posed by a pesticide. Any continuing right to confidentiality in the data submitted by Monsanto to EPA is solely a matter of federal law. Chevron Chemical Co. v. Costle, supra, 641 F.2d at 116; Mobay Chemical Corp. v. Gorsuch, supra, 682 F.2d at 423.

Even if it were true that Monsanto retained a state property right in the data it voluntarily submitted to EPA, Monsanto failed to demonstrate any taking of its property by virtue of EPA's internal consideration and restricted disclosure of the health and safety data to achieve the public purposes described above. In deciding whether a particular governmental action has effected a taking, this Court focuses "both on the character of the action and on the nature and extent of the interference with rights in the [property] as a whole." Penn Central Transp. Co. v. New York City, 438 U.S. 104, 130-131 (1978). Among the factors to be considered are whether the "interference with property can be characterized as a physical invasion by government," and "the extent to which the regulation has interfered with distinct investmentbacked expectations." 438 U.S. at 124. Under the principles established by this Court, a taking is "more readily \* \* \* found when the interference with property can be characterized as a physical invasion by government \* \* \* than when interference arises from

<sup>&</sup>lt;sup>13</sup> Moreover, where, as here, Congress has specifically authorized EPA to consider and disclose health and safety data, the suggestion that the federal government's use of such data is limited by state law contravenes the Supremacy Clause. See *Hancock* v. *Train*, 426 U.S. 167, 179-180 (1976).

some public program adjusting the benefits and burdens of economic life to promote the common good." *Ibid.* In addition, a taking is more readily established where the government regulation destroys all property rights or renders the plaintiff unable to derive any economic benefit from the property. *Andrus* v. *Allard*, 444 U.S. 51, 65-67 (1979). "[T]he denial of one traditional property right does not always amount to a taking. \* \* \* [W]here an owner possesses a full 'bundle' of property rights, the destruction of one 'strand' of the bundle is not a taking, because the aggregate must be viewed in its entirety." *Id.* at 65-66. Tested by these principles, Monsanto has failed to establish a taking.

Here, of course, there is no "physical invasion" of Monsanto's property. In fact, the operation of Sections 3(c)(1)(D) and 10 do not in any way restrain or preclude Monsanto from using its data. The district court specifically found that not only does Monsanto obtain a valuable registration for its data, but it may use the data to develop new products or new uses for old products, to advertise and market its products, to obtain additional domestic and foreign registrations, to defend claims against its products, and to enhance its reputation in the scientific community (App. A, infra, 18a, 21a, 23a).

The district court erred in concluding that Section 3(c)(1)(D) causes a taking because it appropriates Monsanto's fundamental right "to exclude others" from its data. Interference with the right to exclude does not by itself constitute a taking. PruneYard Shopping Center v. Robins, 447 U.S. 74, 84 (1980). The "right to exclude" is merely one "strand" in Monsanto's "bundle" of rights. Since Monsanto retains significant rights in its data (App. A, infra,

18a, 21a, 23a), this limited interference does not constitute a taking. 447 U.S. at 84. At most, the data consideration provisions may result in competition and a concomitant reduction in profits. However, "loss of future profits-unaccompanied by any physical property restriction—provides a slender reed upon which to rest a takings claim." Andrus v. Allard, supra, 444 U.S. at 66. This is particularly true here, where Monsanto retains its primary sources of competitive advantage, including its product and use patents, its advertising and marketing techniques, and lead-time advantages not related to data development (App. A, infra, 18a-21a, 23a). Moreover, Congress did not eliminate all protection for Monsanto's data. Monsanto retains a 10-year exclusive use for data submitted on any new active ingredient registered after 1978 and is entitled to compensation for use of other data submitted after 1969 for a 15-year period. The provision of valuable replacement rights mitigates the burden of the government action and must also be taken into account in considering the impact of regulation. Penn Central, supra, 438 U.S. at 137. The present statutory scheme, designed to promote efficiency and competition while preserving innovation, is a reasonable legislative response for which the principles of "justice and fairness" embodied in the Fifth Amendment do not require compensation. See Agins v. City of Tiburon, 447 U.S. 255, 262-263 (1980); Andrus v. Allard, supra, 444 U.S. at 66.

Similarly, the limited interference with Monsanto's property caused by Section 10, the public disclosure provision, does not constitute a taking. As demonstrated by the district court's findings, the data at issue were "generated primarily for registration purposes" without regard to disclosure (App. A, infra,

21a). In fact, Monsanto has continued and accelerated its research and development efforts despite the 1978 enactment of the disclosure requirements of FIFRA (ibid.). It is therefore clear that disclosure does not destroy Monsanto's ability to earn a reasonable return on its investment; nor does disclosure significantly impair Monsanto's "investment-backed expectations." Furthermore, this Court has upheld similiar schemes providing for release to the public of commercially valuable information to further a legitimate public purpose. Corn Products Refining Co. v. Eddy, 249 U.S. 427, 431 (1919); National Fertilizer Ass'n v. Bradley, 301 U.S. 178 (1937). The Court stated in Corn Products that a "manufacturer or vendor has no constitutional right to sell goods without giving to the purchaser fair information of what it is that is being sold." 14 249 U.S. at 431. Finally, the 1978 Amendments did not eliminate all protection from disclosure of Monsanto's data. Formulas and manufacturing processes are protected in most in-

<sup>14</sup> The district court's conclusion that the public does not need disclosure because of FIFRA's labeling requirements is unsupported. First, the court itself noted that the labels do not contain complete information (App. A, infra, 24a). Second, the court may not ignore Congress' determination that full disclosure of health and safety data is necessary to protect the public health and to enable full public participation in the registration process. Hodel v. Indiana, supra, 452 U.S. at 326. As noted above, many groups such as farm workers, chemical workers, and environmental groups request these data from EPA and retain scientists to review such data. This Court has recognized the propriety and, indeed, the desirability of obtaining public input by making information on regulatory decisions available to the public. See, e.g., FCC v. Schreiber, 381 U.S. 279 (1965); Utah Fuel Co. v. National Bituminous Coal Comm'n, 306 U.S. 56, 60-62 (1939).

stances and EPA ordinarily may not disclose any data to multinational pesticide companies without the submitter's consent. Section 10(g), 7 U.S.C. (Supp. V) 136h(g). These measures attenuate even further Monsanto's taking claim.

In sum, Section 10 strikes a careful balance between industry's interest in proprietary information and the public's interest in evaluating the risks and dangers inherent in pesticide use. Although Section 10 may adjust Monsanto's rights in its property, it does not destroy the property. Monsanto retains significant rights in its data. Thus, while Monsanto

<sup>15</sup> A similar balance has been struck in a great number of federal statutes that authorize or require public disclosure of information submitted by private firms to the government. In particular, many federal statutes provide for disclosure of allegedly "trade secret" information concerning potential hazards to public health. For example, notwithstanding trade secrecy claims, the Toxic Substances Control Act requires public disclosure of "health and safety data" concerning chemical substances and mixtures distributed in commerce (except for manufacturing processes and some formula information). 15 U.S.C. 2613(b); the Clean Air Act requires disclosure of "emission data," 42 U.S.C. (Supp. V) 7607(a) (1); the Federal Water Pollution Control Act requires disclosure of "effluent data," 33 U.S.C. 1319(b); and the Safe Drinking Water Act requires disclosure of all data concerning drinking water contaminants, 42 U.S.C. 300j-4(d). See also 42 U.S.C. 263g (d), requiring disclosure of trade secret data concerning radiation emissions from electronic products such as microwave ovens; 42 U.S.C. 5413(c)(5), requiring disclosure of trade secret data concerning safety-related defects in mobile homes; 46 U.S.C. 1464(d), authorizing disclosure of trade secret information regarding safety defects in boats and boating equipment; and 15 U.S.C. 2217, authorizing trade secret fire protection information to be disclosed when "necessary in order to protect health and safety."

may bear some burden by virtue of this regulation, it is a burden borne to secure "the advantage of living and doing business in a civilized community." Andrus v. Allard, supra, 444 U.S. at 67, quoting Pennsylvania Coal Co. v. Mahon, 260 U.S. 393, 422

(1922) (Brandeis, J., dissenting).

3. Finally, even if operation of Section 3(c)(1)(D) or Section 10 would cause a "taking" of Monsanto's property, Monsanto is not entitled to injunctive relief. A taking will be enjoined as unconstitutional only if it has not been duly authorized, if it serves no public purpose, or if the owner will be denied just compensation for the property taken. See, e.g., Duke Power Co. v. Carolina Environmental Study Group, Inc., 438 U.S. 59, 94 n.39 (1978); Regional Rail Reorganization Act Cases, 419 U.S. 102, 126-127 & n.16 (1974). Under these standards, the district court erred in concluding that Sections 3(c)(1)(D) and 10 are unconstitutional as a violation of the Fifth Amendment.

First, there can be no dispute that EPA's consideration and disclosure of Monsanto's data are duly authorized by Sections 3(c)(1)(D) and 10. Second, as demonstrated above, both sections serve important public purposes. Finally, even if the statute operated to effect a "taking," Monsanto would have an adequate remedy for seeking just compensation under the Tucker Act, 28 U.S.C. 1291. See Chevron Chemical Co. v. Costle, 499 F. Supp. 732, 742-743 (D. Del. 1980), aff'd on other grounds, 641 F.2d 104 (3d Cir.), cert. denied, 452 U.S. 961 (1981); Union Carbide, supra, 632 F.2d at 1019.

The district court's conclusion that Sections 3 and 10 are unconstitutional because Congress withdrew the Tucker Act remedy in FIFRA is unsupported.

The critical question in determining the applicability of the Tucker Act is "not whether the [challenged statutel expresses an affirmative showing of congressional intent to permit recourse to a Tucker Act remedy \* \* \*," but rather whether Congress has "withdrawn the Tucker Act grant of jurisdiction to the Court of Claims to hear a suit involving the [challenged statute] 'founded \* \* \* upon the constitution.'" Regional Rail Reorganization Act Cases, supra, 419 U.S. at 126; emphasis in original. There is no indication in the language or legislative history of the 1978 Amendments to FIFRA that Congress intended to withdraw the Tucker Act remedy. Consequently, there is no basis for the district court's conclusion that the exclusive use and compensation provisions of Section 3(c)(1)(D) were intended to be "the sole compensation" for the operation of Sections 3 and 10.16 The exclusive use and compensation

<sup>16</sup> The district court further erred in suggesting that the Tucker Act remedy is not available because "[n]o monies were allocated by the government to insure that adequate compensation would occur" (App. A, infra, 36a). Such an appropriation is not customary and is in no way a prerequisite to jurisdiction of the Claims Court under the Tucker Act. As this Court stated in Yearsley v. W. A. Ross Construction Co., 309 U.S. 18, 21 (1940), "if the authorized action \* \* \* does constitute a taking of property for which there must be just compensation under the Fifth Amendment. the Government has impliedly promised to pay that compensation and has afforded a remedy for its recovery by a suit in the Court of Claims." Finally, the district court's view (App. A, infra, 36a) that the Tucker Act is not an adequate remedy because FIFRA works an "immediate taking of Monsanto's property as of the passage of the amendments to FIFRA" is unfounded. Obviously, if any taking occurs it occurs only when EPA actually considers Monsanto's data or discloses the data publicly. FIFRA itself does not automati-

provisions were meant to provide incentive for innovation and to spread the costs of producing registration data among all the beneficiaries of such data. The mere provision of exclusive use periods and a compensation scheme does not alone support the conclusion that the Tucker Act remedy has been withdrawn. In the Regional Rail Reorganization Act Cases, this Court rejected a similar contention. 419 U.S. at 127-128. Thus, even if Sections 3(c)(1)(D) and 10 result in a taking of Monsanto's property, the district court erred in declaring them unconstitutional and enjoining their implementation. Regional Rail Reorganization Act Cases, supra, 419 U.S. at 102.

4. In addition to finding the data consideration and disclosure provisions unconstitutional, the district court found the data compensation scheme unconstitutional on the grounds that the binding arbitration scheme does not afford Monsanto just compensation and constitutes a denial of due process in violation of the Fifth Amendment. The court also held that the scheme impermissibly "delegates judicial power to determine property rights disputes without the necessary prerequisites of Article III of the Constitution" (App. A, infra, 34a-35a). These issues are not ripe for judicial review and should not have been reached by the district court because Monsanto has not been a party to any arbitration under the section. Babbitt v.

cally confiscate Monsanto's data. FIFRA merely provides for EPA's consideration and disclosure of the data under specified circumstances. Moreover, to the extent the district court's holding rests on concern that compensation, if required, will not precede the alleged "taking," the holding has no merit. The Fifth Amendment does not require that compensation precede the taking. Hurley v. Kincaid, 285 U.S. 95, 104 (1932).

United Farm Workers National Union, 442 U.S. 289 (1979).

Moreover, these arguments are all without merit. First, as discussed above, the intra-industry compensation scheme was not meant to provide Monsanto "just compensation" within the meaning of the Fifth Amendment, since no taking requiring compensation has occurred. Second, this Court has consistently upheld, against due process claims, the constitutionality of statutes with mandatory arbitration provisions. See Andrews v. Louisville & Nashville R.R., 406 U.S. 320, 322 (1972); Walker v. Southern Ry., 385 U.S. 196, 198 (1966); Hardware Dealers Mutual Fire Insurance Co. v. Glidden Co., 284 U.S. 151 (1931). See also Country-Wide Insurance Co. v. Harnett, 426 F. Supp. 1030 (S.D. N.Y.) (three-judge court), aff'd without opinion, 431 U.S. 934 (1977). Courts regularly have upheld such arbitration requirements against claims that they provide for the determination of certain rights by nonjudicial bodies with only limited judicial review. See Crane v. Hahlo, 258 U.S. 142 (1922); Ludwig Honold Mfg. Co. v. Fletcher, 405 F.2d 1123 (3d Cir. 1969); Edwards v. St. Louis-San Francisco R.R., 361 F.2d 946 (7th Cir. 1966). See also Switchmen's Union v. National Mediation Bd., 320 U.S. 297, 300-301 (1943). Contrary to the district court's holding (App. A, infra. 34a-35a). the arbitration scheme in Section 3(c)(1)(D) does not amount to an unlawful delegation of judicial power without the prerequisites of Article III. The district court's reliance on Northern Pipeline Construction Co. v. Marathon Pipe Line Co., No. 81-150 (June 28, 1982), is misplaced. In contrast to the 1978 Bankruptcy Act, FIFRA does not vest arbitrators with the authority to adjudicate common law

disputes or any rights other than those established solely by Section 3(c)(1)(D) itself. As the plurality opinion in *Northern Pipeline* states (slip op. 33; footnote omitted):

[W]hen Congress creates a statutory right, it clearly has the discretion, in defining that right, to create presumptions, or assign burdens of proof, or prescribe remedies; it may also provide that persons seeking to vindicate that right must do so before particularized tribunals created to perform the specialized adjudicative tasks related to that right.

Finally, even if this Court were to resolve the Article III issue in Monsanto's favor, that would not justify enjoining the entire Section 3(c)(1)(D), but only the limitation on judicial review in the fourth sentence of Section 3(c)(1)(D)(ii). See 2 C. Sands, Sutherland Statutory Construction § 44.04 (4th ed. 1973); Section 30, 7 U.S.C. (Supp. V) 136x (severability).

#### CONCLUSION

Probable jurisdiction should be noted.

Respectfully submitted.

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AUGUST 1983

#### APPENDIX A

## IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF MISSOURI EASTERN DIVISION

No. 79-366 C (1)

MONSANTO COMPANY, PLAINTIFF

vs.

ACTING ADMINISTRATOR, UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, DEFENDANT

[Filed Apr. 19, 1983]

## **MEMORANDUM**

This matter is before the Court for a decision on the merits after a bench trial which spanned weeks and generated a 690 page transcript, numerous depositions, exhibits and affidavits. At issue is the constitutionality of Sections 3(c)(1)(D), 3(c)(2)(A) and Sections 10(b) and 10(d) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended in 1978, 7 U.S.C. § 136 et seq. Plaintiff seeks an injunction and declaratory judgment blocking operation of the Sections in question. Both parties have ably presented and briefed their respective positions and have provided the Court with a concise and thorough foundation for its decision.

Pursuant to Rule 52 of the Federal Rules of Civil Procedure, the Court hereby makes the following findings of fact and conclusions of law. Any finding of fact equally applicable as a conclusion of law is hereby adopted as such and, conversely, any conclusion of law applicable as a finding of fact is adopted as such.

## Findings of Fact

- 1. Plaintiff, Monsanto Company, is incorporated in the State of Delaware and has its principal place of business in St. Louis County, Missouri. Plaintiff owns and operates its principal corporate and administrative offices, and its major research facilities in St. Louis County, Missouri. It is licensed to do business in the State of Missouri and resides in this judicial district.
- 2. Defendant is the Acting Administrator of the United States Environmental Protection Agency (hereinafter EPA), and is charged with the implementation, administration and enforcement of the Federal Insecticide, Fungicide and Rodenticide Act. Defendant is sometimes hereinafter referred to as the "Administrator".
- 3. Since FIFRA was first enacted in 1947, it has required the registration of all pesticides shipped in interstate commerce. In order to obtain the registration of a pesticide under FIFRA an applicant was required to support its application for registration with extensive research and test data demonstrating that the product would comply with FIFRA, that is, that the pesticide was effective for its recommended uses, and that it would perform its intended functions without unreasonable adverse effects on man. vertebrate animals and desirable vegetation. If use of the pesticide for which registration was sought could result in residues in or on raw agricultural commodities, the applicant was also required to submit in support of its application for registration extensive research and test data relating to the pro-

posed application of the pesticide, its toxicity, the manner in which it was metabolized, its degradation, and its residues. This information was also required to be submitted in a petition for a tolerance for the

pesticide for which registration was sought.

Until 1970, the Secretary of the United States Department of Agriculture (hereinafter USDA) administered FIFRA. Also, until 1970, the Secretary of Health, Education and Welfare, by and through the Food and Drug Administration (hereinafter FDA), was authorized to establish tolerances for pesticide chemicals in or on raw agricultural commodities under Section 408 of the Food, Drug and Cosmetic Act, 21 U.S.C. § 346(a). These administrative functions of the USDA and FDA were transferred to EPA in December, 1970, by Reorganization Plan No. 3 of 1970, 35 Fed. Reg. 15623 (1970).

4. The term "pesticide" is defined in Section 2(u) of FIFRA to mean (1) any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest, and (2) any substance or mixture of substances intended for use as a plant regulator, defoliant, or dessicant." (FIFRA Section 2(u)).

The person holding the registration that permits the product to be sold or distributed is known as a

"registrant."

5. One of the two basic kinds of pesticide products is an "end-use product" or "formulated product" designed to be used as sold or after dilution by the user against pests. An end use product contains at least one active ingredient which is defined in Section 2(a) of FIFRA as "an ingredient which will prevent, destroy, repel or mitigate any pest" or which will defoliate, dessicate or regulate the growth of

plants. In order for an end use product to be used against pests and plants the active ingredient normally must be combined with "inert ingredients" which dissolve, dilute or stabilize the active ingredient or otherwise improve its pesticidal performance.

6. A second basic kind of pesticide product is a "manufacturing-use product" which is a product designed to be used to manufacture an end use product. A manufacturing use product generally is a relatively pure form of the active ingredient and is some-

times referred to as a technical product.

7. Approximately 40,000 pesticide products are currently registered under FIFRA. Most of these registered products are end use products (about 2,500 are registered for manufacturing use). Many of these end use products are very similar, containing the same active ingredient and closely similar inert ingredients.

- 8. A relatively few firms actually produce all the active ingredients. Of the more than 4,000 registrants, therefore, most are engaged in producing end-use products, using active ingredients they purchase (these firms are usually referred to as "formulators"). Some firms, such as Monsanto, produce both active ingredients and end-use products. A firm which produces an active ingredient may use it solely for incorporation into its own end-use products, may sell it (in the form of a manufacturing-use product) to formulators, or may do both.
- 9. Most of the research and testing on pesticides, and invention and development of new active ingredients, has been done by a few, relatively large companies of which Monsanto is one. Most, if not all, firms of this type, including Monsanto, are engaged in foreign or multinational pesticide sales.

10. Monsanto is involved in research and development activities to attempt to develop new pesticide products. These research and development efforts have resulted in the expediture of millions of dollars by Monsanto and their efforts have resulted by the granting of patents for many of the new active in-

gredients which Monsanto has developed.

11. A company's decision to develop pesticides requires it to make major commitments long before it can anticipate developing a commercial pesticide and even longer before it can expect any return on its investment. First, the company must synthesize, test and evaluate candidate pesticides typically for 4 to 8 years before it will identify a commercial candidate. It must then conduct extensive research for at least 6 additional years, including 2 years to obtain registration, before it can anticipate first marketing a product. Generally, a further 4 to 8 years will elapse before that product reaches a point where its costs of discovery, development and commercialization have been recovered. Second, the company must commit to the employment of a large scientific research group representing many disciplines, and to the acquisition of the necessary physical facilities and sophisticated equipment to conduct the intensive research required to assure some reasonable probability of success in discovering and commercializing a candidate pesticide. Third, any such company must usually commit to the expenditure of \$5 million to \$15 million annually for several years before it will develop a potential commercial pesticide candidate. Even then, it will not know whether the candidate will become a commercial product until it has conducted further evaluation for an additional four or more years. This further evaluation could dictate

that the candidate be rejected at any point during its development, even in the final year of its further evaluation. A key element in the above analysis is whether the chemical can be patented, thereby assuring Monsanto monopoly protection for the patented chemical, use or process during the period of the

patent.

12. Once a target is selected, a company must devise extremely efficient, unique and technically sound ways of determining what compounds should be synthesized. The Company's chemists are not only concerned with synthesizing new chemicals, but equally important, are concerned with new chemical processes, techniques, and methods of synthesis to facilitate their invention of such new chemicals with commercial potential. Once a company decides that a new area of chemistry might be fruitful, these chemists then proceed to develop and synthesize new compounds in that area of chemistry. These new compounds are referred to biologists who determine whether they are biologically active and whether they are pesticide candidates. This biological information is crucial in making the difficult technical judgment whether a compound is worthy of further study. The biologists and the chemists then examine and discuss the results to determine which directions, if any, offer further leads. Using the knowledge obtained from these discussions, the chemists synthesize more new compounds in the directions in which leads are expected. This constant dialogue takes place between literally dozens of organic chemists and biologists and is what ultimately produces the lead which results in a new commercial pesticide.

Decisions on most of the thousands of chemicals synthesized by plaintiff are made after an initial evaluation called a primary screen which allows plaintiff to determine the probability of a compound becoming commercially successful. With most compounds, this probability is virtually zero, and these compounds are rejected. However, Monsanto can and usually does seek patents on any chemicals with commercial potential, even if they do not themselves decide to develop those chemicals.

13. When EPA registers a pesticide product under FIFRA, what it actually is doing is approving the composition and labeling for that product and allowing that product to then be sold with the approved labeling being use.

14. A label must contain: 1) general information such as the name of the company, the type of product, and the registration number; 2) hazard statements; 3) directions for use; and 4) limitations on use.

15. The hazard statements required to appear on the label include precautionary statements and a statement of physical hazards. The precautionary statements, inter alia, inform the user of the relative toxicity of the pesticide and set out an antidote in the event a person is poisoned by the pesticide. The statement of physical hazards contains information regarding things such as the flammability of the product, how the product should be stored, and how the container should be disposed.

16. The directions for use set forth the manner in which the pesticide is to be used. It is illegal for any person to use a pesticide for any purpose other than that stated in the directions for use. With respect to agricultural chemicals the directions for use inform the user of the type of crops to which the pesticide may be applied, the pests which it can be used to control, the dosage rate which must be used, and the method of application.

17. The limitations on use include restrictions such as a pre-harvest interval which provides that the pesticide must be applied more than a certain number of days before it is harvested or a rotational crop limitation which provides that specifically-named crops should not be planted for a certain time in the field to which the pesticide has been applied.

18. FIFRA was originally enacted in 1947 (P.L. 80-140), 61 Stat. 163). Under the terms of the original statute pesticide manufacturers were required to obtain a registration from the United States Department of Agriculture (USDA) before distributing or selling their pesticide products in interstate commerce. 7 U.S.C. § 135(a) (1970).

19. In order to obtain a pesticide registration under 1947 FIFRA the applicant for registration was required to file with USDA a statement which included the following information:

- the name and address of the applicant for registration and the name and address of the person whose name will appear on the label, if other than the applicant for registration;
  - (2) the name of the economic poison;
- (3) a complete copy of the labeling accompanying the economic poison and a statement of all claims to be made for it, including the directions for use; and
- (4) if requested by the Administrator, a full description of the tests made and the results thereof upon which the claims are based.

## 7 U.S.C. § 135(a) (1970).

The test data required under 7 U.S.C. § 135b(a)(4) essentially consisted of efficacy data and limited tests concerning the health and safety dangers of the pesticide products, (particularly its acute toxicity).

20. On October 20, 1972, FIFRA was amended by the Federal Environment Pesticide Control Act of 1972, (Pub. L. No. 92-516, 92d Cong., 2d Sess., October 21, 1972), (FEPCA). Pursuant to this amendment, the registration requirements were extended to pesticides shipped in intrastate commerce and authority was provided for the classification of pesticides and the regulation of their use. All of the requirements for the submission of research and test data were retained. Moreover, the data to be submitted under the 1972 amendments was the same general kinds of information that were required under the 1947 Act. The requirements for obtaining a registration were also strengthened so that the 1972 amendments were described as having "changed FIFRA from a labeling law into a comprehensive regulatory statute that . . . more carefully control[s] the manufacture, distribution and use of pesticides." H.R. Rep. No. 92-511, 92 Cong., 1st Sess. 4 (1971).

21. Section 3(c)(1)(D) of FIFRA sets forth the requirements for submission by an applicant for registration of information, research and test data to support his application. This Section as enacted in

1972 provided as follows:

(D) if requested by the Administrator, a full description of the tests made and the results thereof upon which the claims are based, except that data submitted in support of an application shall not, without permission of the applicant, be considered by the Administrator in support of any other application for registration unless such other applicant shall have first offered to pay reasonable compensation for producing the test data to be relied upon and such data is not protected from disclosure by section 10(b). If the

parties cannot agree on the amount and method of payment, the Administrator shall make such determination and may fix such other terms and conditions as may be reasonable under the circumstanecs. The Administrator's determination shall be made on the record after notice and opportunity for hearing. If the owner of the test data does not agree with said determination, he may, within thirty days, take an appeal to the federal district court for the district in which he resides with respect to either the amount of the payment or the terms of payment, or both. In no event shall the amount of payment determined by the court be less than that determined by the Administrator.

22. In Section 3(c)(1)(D) as enacted in 1972, Congress authorized the Administrator to use and consider information, research and test data submitted by a previous applicant for registration to support the application of a subsequent application, but only upon satisfaction of two preconditions. Although the Administrator could use any and all data previously submitted under FIFRA for purposes of determining the adequacy of the particular data submitted by an applicant to obtain a specific registration, the Administrator could not use any of the previously submitted data for the benefit of such applicant, that is, in support of his application, unless the owner of the previously submitted data first granted his permission or the applicant for whose benefit the previously submitted data would be used offered to pay reasonable compensation to its owner. If, however, any of the previously submitted data to be considered in support of the application contained or related to trade secrets or other information protected from disclosure by Section 10(b) of FIRFA, including confidential commercial information, then without the owner's permission it could not be used at all.

- 23. Section 10 of FIFRA relates to the information, research and test data of an applicant which contains or relates to trade secrets or other confidential or privileged commercial or financial information. This data was prohibited from disclosure under Section 10 as enacted in 1972 which then provided in part as follows:
  - (b) Disclosure. Notwithstanding any other provision of this Act, the Administrator shall not make public information which in his judgment contains or relates to trade secrets or commercial or financial information obtained from a person and privileged or confidential, except that, when necessary to carry out the provisions of this Act, information relating to formulas of products acquired by authorization of this Act may be revealed to any Federal agency consulted and may be revealed at a public hearing or in findings of fact issued by the Administrator. (emphasis added).
- 24. In an attempt to resolve controversy which had developed about the effective date of Section 3(c)(1)(D) and the data to which that section applied, Congress enacted FIFRA of 1975, Pub. L. No. 94-140, 89 Stat. 725 (1975 amendments). The 1975 amendments revised Section 3(c)(1)(D) to read in pertinent part as follows:

Each applicant for registration of a pesticide shall file with the Administrator a statement which includes—

(D) if requested by the Administrator, a full description of the tests made and the results thereof upon which the claims are based, except that data submitted on or after January 1, 1970. in support of an application shall not, without permission of the applicant, be considered by the Administrator in support of any other appleation for registration unless such other applicant shall have first offered to pay reasonable compensation for producing the test data to be relied upon and such data is not protected from disclosure by Section 10(b). This provision with regard to compensation for producing the test data to be relied upon shall apply with respect to all applications for registration or reregistration submitted on or after October 21, 1972. (Emphasis added).

25. The 1978 amendments completely rewrote Section 3(c)(1)(D) to remove the "trade secret" prohibition established by the 1972 amendments. The result of this rewriting is now embodied in Section 3(c)(1)(D). That scheme no longer prohibits the consideration of data based on its status as a trade secret but rather creates a system whereby the "age" of the data, and the "newness" of the active ingredient to which the data relates, determine the amount of protection which will be afforded. By its terms the 1978 Act established three categories of test data available for consideration by EPA under varying conditions. With respect to data submitted to support a registration application initially granted after September 30, 1978 (post-1978 data), the Administrator may not consider such data to support an application of another person (applicant), without the permission of the original data submitter, for a period of

ten years following the initial registration. Therefore, data submitters are entitled to a ten-year period of "exclusive use" for post-1978 data. § 136(a)(c)(1)(D)(i). With respect to data submitted after December 31, 1969 (post-1969 data), the Administrator may consider such data to support an application by another person, without the permission of the original data submitter, for a period of fifteen years following submission of the data only if the subsequent applicant has offered to compensate the original data submitter. Disputes as to compensation are submitted to binding arbitration, unreviewable by any court absent fraud or misrepresentation. An original data submitter who refuses to participate in the arbitration proceeding forfeits the right to compensation. Thus, data submitters are entitled to a fifteenyear period of compensation for use of post-1969 data. Data submitted after 1978, for which ten years of exclusive use is assured, also receives five years of compensation upon expiration of the exclusive use period. Finally, data submitted before 1970 may be considered by the Administrator to support the application of another application without the permission of the original data submitter and without an offer of compensation having been made. Chevron Chemical Co. v. Costle, 499 F. Supp. 732, 735-36, 740 (D. Del. 1980), aff'd 641 F.2d 104 (3rd Cir.), cert. denied, 452 U.S. 961 (1981).

26. The amendments to Section 3(c) (1) (D) were enacted because Congress believed that the "trade secret" prohibition created by the 1972 amendments was a deterrent to desirable competition in the manufacture and sale of pesticide products in commerce and in practice acted as a *de facto* extension of the period of patent protection beyond the 17-year period established by statute. S.Rep. No. 95, 334 at 3, 8, 31.

27. The "exclusive use" and compensation provisions in Section 3(c)(1)(D) were viewed as an appropriate reward for innovation while providing, at the same time, a fair and less expensive procedure for producing pesticide safety data. 124 Cong. Rec. § 15,

303-04 (Sept. 18 daily ed.)

28. Section 3(c)(2) of FIFRA was redesignated Section 3(c)(2)(A) by the 1978 amendments. Prior to the 1978 amendments, Section 3(c)(2) was limited by Section 10 which, in Section 10(b), absolutely prohibited the public disclosure of information containing or relating to trade secrets or confidential commercial information. Section 3(c)(2)(A) continues to be limited by Section 10, but Section 10 as amended in 1978 provides that in Section 10(b) that:

Disclosure: Notwithstanding any other provision of this Act, and subject to the limitations in subsections (d) and (e) of this section the Administrator shall not make public information which in his judgment contains or relates to trade secrets or commercial or financial information obtained from a person and privileged or confidential, except that, when necessary to carry out the provisions of this Act, information relating to formulas of products acquired by authorization of this Act may be revealed to any Federal agency consulted and may be revealed at a public hearing or in findings of fact issued by the Administrator (emphasis added).

The 1978 amendments also added a new Section 10(d) which provides in pertinent part as follows:

Limitations: (1) All information concerning the objectives, methodology, results, or significance of any test or experiment performed on or with a registered or previously registered pesticide or its separate ingredients, impurities, or degradation products, and any information concerning the effects of such pesticide on any organism or the behavior of such pesticide in the environment, including, but not limited to, data on safety to fish and wildlife, humans and other mammals, plants, animals, and soil, and studies on persistence, translocation and fate in the environment, and metabolism, shall be available for disclosure to the public. Provided, that the use of such data for any registration purpose shall be governed by Section 3 of this Act. Provided further, that this paragraph does not authorize the disclosure of any information that—

(A) discloses manufacturing or quality control processes,

(B) discloses the details of any methods for testing, detecting, or measuring the quantity of any deliberately added inert in-

gredient of a pesticide, or

(C) discloses the identity or percentage quantity of any deliberately added inert ingredient of a pesticide, unless the Administrator has first determined that disclosure is necessary to protect against an unreasonable risk of injury to health or the environment. (emphasis added)

29. The 1978 amendments added a new Section 10(g) prohibiting disclosure to foreign and multinational companies which provides in pertinent part as follows:

Disclosure to Foreign and Multinational Pesticide Producers. (1) The Administrator shall not

knowingly disclose information submitted by an applicant or registrant under this Act to any employee or agent of any business or other entity engaged in the production, sale, or distribution of pesticides in countries other than the United States or in addition to the United States or to any other person who intends to deliver such data to such foreign or multinational business or entity unless the applicant or registrant has consented to such disclosure. The Administrator shall require an affirmation from any person who intends to inspect data that such person does not seek access to the data for purposes of delivering it or offering it for sale to any such business or entity or its agents or employees and will not purposefully deliver or negligently cause the data to be delivered to such business or entity or its agents or employees. Notwithstanding any other provision of this subsection, the Administrator may disclose information to any person in connection with a public proceeding under law or regulation, subject to restrictions on the availability of information contained elsewhere in this Act, which information is relevant to the determination by the Administrator with respect to whether a pesticide, or any ingredient of a pesticide causes unreasonable adverse effects on health or the environment.

(2) The Administrator shall maintain records of the names of persons to whom data are disclosed under this subsection and the persons or organizations they represent and shall inform the applicant or registrant of the names and affiliation of such persons.

- (3) Section 1001 of Title 18 of the United States Code shall apply to any affirmation made under paragraph (1) of this subsection.
- 30. Section 10(f) is another new section that was added by the 1978 amendments. That section establishes a criminal penalty more stringent than that provided by the Trade Secrets Act, 18 U.S.C. § 1908, for wrongful disclosure of confidential or trade secret data by a government employer or contractor. (FIFRA Section 10(f), 7 U.S.C. § 136h(f).

31. The changes in 10(b), (d) were designed to further the public's right to know the basis for agency registration decisions. 123 Cong. Rec. § 13,091 (July 29, 1977 daily ed.). Also notable is the fact that a data submitter's manufacturing or quality control processes is not to be disclosed.

32. In order to support the registration of its products under FIFRA, as amended in 1978, plaintiff submits to defendant, information, research and test data of the following types: (1) efficacy studies: (2) phototoxicity studies; (3) metabolism and residue studies; (4) environmental chemistry studies; (5) toxicology studies; (6) fish and wildlife studies; and (7) manufacturing studies and information. This the data that Section 3(c)(2) as limited by Section 10, discloses. The research expended by Monsanto to provide the above data to register its products is not only time staking but involves the expertise of highly trained scientists. Monsanto utilizes sophisticated methods to adduce the necessary data. and the evidence indicated, that Monsanto is one of the leaders in the field, especially with respect to Monsanto's use of radiolabeling. Monsanto maintains that the direct historical cost incurred to develop the information, research and test data submitted by it

under FIFRA to secure, maintain and expand the registration of its products is in excess of \$23,600,000.00. The Court finds that figure a fair approximation of Monsanto's costs in this area.

33. Much of the information, research and test data submitted by plaintiff to the EPA under FIFRA is and has been confidentially maintained by plaintiff with stringent security measures taken to preserve its secrecy.

34. The information, research and test data developed by and submitted by plaintiff under FIFRA is used by plaintiff to develop additional formulations

and to expand uses of its registered products.

35. Development of plaintiff's information, research and test data by a competitor would be extremely difficult, if at all possible, and in any event would require the exercise of highly sophisticated scientific expertise and ingenuity for thousands of manyears as well as the expenditure of enormous sums of money.

36. Disclosure of plaintiff's information, research and test data certainly enhances a competitor's ability to conduct research on identical or similar competing products and might result in the development

of new products.

37. A number of other companies are, as is plaintiff, engaged in the discovery and development of pesticide products in the United States and worldwide, and these companies compete with plaintiff.

38. Pursuant to 35 U.S.C. § 134, the issuance of a patent grants the patentee the exclusive right to make, use and sell the patented invention (in this case the pesticide chemical, use or formulation) for a 17 year period.

As previously indicated, patents on newly discovered pesticide compounds are normally applied for

early in the development process and before the substantial amounts of information, research and test data submitted to support a registration are generated. The patent, if issued, does not provide protection for the research and test data submitted in sup-

port of an application for registration.

39. Upon expiration of the 17-year period of patent protection, the patent law no longer prohibits companies from making, using, or selling the formerly patented product. In the case of formerly patented pesticide chemicals, the expiration of the patent period by itself is not sufficient to allow companies to legally sell pesticide products containing that active ingredient, because FIFRA requires those companies must first obtain a pesticide registration before selling their pesticide products. Under the 1972 and 1975 amendments, a data submitter could prevent a subsequent application from relying on data it had submitted to EPA and thereby prevent that applicant from obtaining a registration unless the applicant submitted his own information.

40. Monsanto frequently enjoys most of the full term of patent protection after it has initially registered a pesticide chemical. Further, new uses, manufacturing processes, formulations, or other elements important to the commercial success of the product

may also be eligible for patent protection.

41. During the period of patent monopoly protection, Monsanto and other pesticide companies are also able to establish other significant competitive advantages which last beyond the period of patent protection. During the period of patent protection Monsanto is able to establish "name recognition" for its trademarks through advertising as well as the "goodwill" which it receives as the only supplier of an effective product.

42. In making its decision to proceed with the development of a pesticide, Monsanto must consider a variety of factors. Included among the factors which Monsanto must consider are the availability of patent protection, the availability of raw materials, the environmental control requirements which will be imposed on the manufacture of the chemical, and the potential market for the chemical. Successful development in light of these factors can greatly enhance Monsanto's competitive advantage.

43. During the period of development of data to support an application for pesticide registration of an active ingredient, Monsanto must also secure a reliable source of raw material supplies, develop manufacturing technology and build large-scale production facilities, secure necessary environmental and other permits, develop formulations for the marketed product, and establish markets. All of these steps together require a period of several years and represent a "lead time" advantage which Monsanto enjoys over any competitor.

44. Before a "me-too" applicant can secure a registration which involves Agency consideration of Monsanto data, that applicant must supply its own formula and manufacturing process information and all the data necessary to establish that its product is actually like the Monsanto product in every relevant respect from the standpoint of applicability of the data submitted by Monsanto.

45. Monsanto is engaged in the business of manufacturing and selling synthetic fibers and chemicals. Monsanto is divided into five operating companies (units). One such unit, Monsanto Agricultural Products Company manufactures and sells pesticides. In 1980 it accounted for approximately sixteen per cent (16%) of its operating income. That substantial

percentage of plaintiff's operating income is primarily due to the sales and profits of plaintiff's herbicides. The costs of research and development within the Agricultural Products Company are ordinary business expenses for tax purposes.

46. Despite the passage of the 1978 amendments to FIFRA, Monsanto continues to expand research and development and to submit extensive data to EPA.

- 47. Although Monsanto has refused to acknowledge the economic value to it conferred by the compensation provisions of § 3(c)(1)(D), it has received offers to pay from potential "me-too" registrants. EPA data guidelines provide the means for companies like Monsanto and "me-too" registrants to identify what kinds of studies are compensable. However, there are no discernible guidelines outlining the factors which constitute just compensation for use of Monsanto's data.
- 48. The data which Monsanto submits in support of its applications, although generated primarily for registration purposes, also serves other purposes including to provide information necessary to protect the workers who manufacture the chemical and the researchers who test it, to use for defensive purposes in product liability lawsuits, to spur further research and development, and to obtain registrations in foreign countries.
- 49. Most of Monsanto's competitors in the research and development field are large foreign or multinational companies like itself. Thus, Section 10(g) of FIFRA does not directly authorize disclosure to Monsanto's foreign or multinational competitors of health and safety data otherwise disclosable to the public pursuant to Section 10(d). Still, the Court registers considerable doubt as to the effectiveness of FIFRA's disclosure provisions. Indeed, EPA all but

admitted that there were certain situations in which the agency could not block the disclosure of information to multinational corporations (e.g., those multinational corporations that take over a national corporation) or foreign governments presumably even those governments unfriendly to the interests of the United States.

- 50. Much of plaintiff's information, research and test data that it has submitted under FIFRA to EPA and its predecessor agencies contains or relates to trade secrets as defined by the Restatement of Torts and Confidential, commercial information.
- 51. Plaintiff has certain property rights in its information research and test data.
- 52. Information, research and test data submitted under FIFRA can be evaluated by the EPA without the necessity of public disclosure.
- 53. Groups such as environmental organizations interested in protecting man and the environment from the effects of these dangerous pesticide chemicals, farmworkers' unions which serve to protect the interest of farmworkers who are directly exposed to the pesticides used in the fields where they work, and union groups which represent the workers in the chemical industry who manufacture pesticides, are interested in reviewing pesticide health and safety data. Indeed, many of the disclosure requests that EPA receives pursuant to Section 10 of FIFRA come from these types of groups.
- 54. Except for amounts of data within the manufacturing area, for example, the confidential statement of formula and the manufacturing process, the good portion of plaintiff's information, research and test data falls within that which would be disclosed to the public under Section 10 of FIFRA.

55. Defendant now has pending before her applications for registration submitted by plaintiff's competitors which will require defendant to use plaintiff's information, research and test data in order to grant them. Unless the relief sought by plaintiff is granted, defendant will use plaintiff's information, research and test data, including information, research and test data which is or contains trade secrets to grant these registrations as provided by Section 3(c) (1) (D) of FIFRA and, thereafter, will disclose such information, research and test data to members of the public as provided by FIFRA Section 10.

56. Monsanto would suffer a competitive advantage should its competitors obtain Monsanto's health and research product. The use or consideration for or disclosure to any third party by defendant of plaintiff's data will irreparably injure plaintiff in the conduct of its business and win confer an immediate and substantial competitive advantage upon its competitors, including foreign government-owned pesticide producers by eliminating the significant leadtime advantages enjoyed by plaintiff, by advancing significantly the state of such competitors' technology and by permitting the registration of their products. both in the United States and foreign countries, without their incurring the enormous expenditure of time and money for research and development which plaintiff has incurred.

57. Nothing in FIFRA Section 3 or Section 10 limits Monsanto's continued use of its research results to develop new products or new uses for old products, to advertise and market its products, to defend against legal or advertising claims adverse to the product, or to enhance Monsanto's reputation in the scientific community.

58. EPA has adopted internal and published interim procedures to implement the disclosure provisions of § 10. The procedures provide a mechanism to identify persons to whom disclosure is prohibited by § 10(g). They also permit full access by data submitters to the district court review provisions of § 10 prior to release of any information claimed confiden-

tial by the submitting company.

59. Through the addition of Section 10(d), Congress has now made available for disclosure efficacy data, metabolism and residue data, environmental chemistry data, toxicology data and fish and wildlife data, regardless of whether that data qualifies as "trade secret" under the Restatement of Torts standards. In Section 10(d)(1)(A), (B) and (C), however, Congress has prohibited EPA from routinely disclosing "any information that (A) discloses manufacturing or quality control processes. . . ."

60. The dan that is available to be disclosed under Section 10(d)(1) has health and safety significance.

- 61. Labeling provides instructions for handling and general indications of the acute toxicity of the product, but does not elaborate the scientific basis for this information.
- 62. Scientific training is required to understand much of the Section 10 data because of its technical nature.
- 63. The EPA has the ability to obtain independent scientific review and evaluation of the information, research and test data submitted to it under FIFRA in a manner which does not compromise its confidentiality and the competitive advantage to the company which said information, research and test data provides without the necessity of public disclosure by utilizing such groups as the Scientific Advisory Panel

of EPA which consists of outside scientists who are experts in certain fields including toxicology, medicine, metabolism and physiology. The Scientific Advisory Panel reviews information, research and test data presented to it by both EPA and companies and makes recommendations to EPA for actions to be taken, which EPA may or may not choose to follow.

64. In cases where an applicant was seeking a registration for a product or use not previously registered under FIFRA, USDA generally required that applicant to supply efficacy data and limited health and safety data to demonstrate that the product for which registration was sought was safe and effective when used as directed. However, the majority of the applications received by USDA, were for pesticide products and uses which were the same or substantially the same as products that had previously been registered. This type of application is commonly referred to as a "me-too" application.

65. The Pesticide Regulation Division of the USDA was divided into several branches, one of which was the Registration Branch. The Registration Branch was responsible for the review of applications for pesticide registrations. The registration branch was divided into several sections which divided the review function by types of pesticide.

66. Plaintiff's witness, Dr. Harry Hays, was director of the Pesticide Regulation Division from 1966-1969. Mr. Gregory A. Rohwer, also plaintiff's witness, was detailed to the Pesticide Regulation Division as Acting Director of that division between 1969 and 1970. Mr. Harold G. Alford was an Assistant Director of the Pesticide Regulation Division in charge of the registration branch between 1960-1970 when the pesticide registration responsibilities were

transferred from USDA to EPA. At various times between 1967-1970, defendant's witness, Mr. Ray Landolt, worked in the registration branch and actually participated in the process of reviewing

applications.

67. In order to carry out the established use patterns system of registration, the USDA established by regulation a list of active ingredients for which there was adequate toxicology data available to support a registration. This list, known as "Interpretation 18" was first published in 1949 and was updated in 1954 and 1962. Each entry identified the active ingredient and contained information concerning the registered uses of the pesticide and its formulations as well as a sample of appropriate hazard labeling for products containing that active ingredient. This list apparently included both patented and unpatented products, including Monsanto products and the majority of data in support of these pesticide registrations was already in the public domain.

68. During the period that the USDA administered FIFRA, it was its policy that the data developed and submitted by companies such as plaintiff be maintained confidentially by the USDA and was not to be disclosed without the permission of the data

submitter.

69. During the period the USDA administered FIFRA, it was also its *policy* that the data developed and submitted by companies such as plaintiff could not be used to support the registration of another's product without the permission of the data submitter.

70. Two former Directors of the Pesticide Regulation Division know of no instance in which any such use without permission was made. Further, if any such use without permission was made, it was con-

trary to the policy of the Pesticides Regulation Division. No person in the Division other than the Director had the authority to adopt or change the policy of the Division.

71. Data in the published literature or which had been developed by governmental agencies could be used by all without restriction, and for older products such as DDT this data was often sufficient to support registration without requiring the submission of data by an applicant.

72. These older products referred to in Finding of Fact No. 71 were known as "commodity" products. Examples of such products included 2,4-D and

2,4,5-T.

73. Plaintiff and other companies were granted pesticide registrations for certain of these commodity products without the submission of data in support of said registration because publicly available data supported said registrations. This was consistent with the USDA policy as set forth in Finding No. 69.

74. Prior to October 21, 1972, with the exception of two registrations granted to Aceto Chemical Co., Inc., on July 17, 1972 and July 24, 1972, no competitor of plaintiff was granted a pesticide registration on other than a commodity product, based on data

submitted by plaintiff.

75. Plaintiff had no knowledge of either of the pesticide registrations referred to in Finding No. 74,

prior to their being granted.

76. Plaintiff was not advised of either of the applications for registration referred to in Finding No.

74, prior to their being granted.

77. The evidence in the record did not establish that at any time plaintiff had any knowledge that the policy of USDA referred to in Finding No. 69 regarding treatment of information, research and test

data developed and submitted by a pesticide producer was ever violated. Further, the evidence establishes that two former Directors of the Pesticide Regulation Division were unaware of any violation of said policy.

78. The evidence establishes that if any policy other than that referred to in Finding No. 69, regarding information, research and test data developed and submitted by a pesticide producer was ever in effect at any time, such policy was never written and made available to the public or Monsanto.

## Conclusions of Law

The Court has jurisdiction over this matter pursuant to 28 U.S.C. § 1331(a), 7 U.S.C. § 136n(a).

In order for Monsanto to succeed in this lawsuit, it must establish the following: (1) that Monsanto has an entitlement created by federal or state law in the data it submits; (2) that EPA's use and public disclosure of said data constitutes a "taking" within the meaning of the Fifth Amendment; (3) that the compensation provisions provided by FIFRA are inadequate and that a Tucker Act remedy is not available. Monsanto must prevail on each of these issues in order for declaratory and injunctive relief to be proper. The Court will employ the above analysis to each of the challenged provisions (§ 3—Use Authority), (§ 10—Disclosure Authority).

Plaintiff maintains that two grounds exist for finding its data is constitutionally protected property. First, Monsanto points to federal law where it is contended that regulations and statutes prohibited the disclosure of a registrant's research and data. Second, Monsanto looks to Missouri's protection of trade secrets as defined in § 757 of the Restatement of

Torts (1939).

The evidence in this lawsuit showed that under the 19-7 version of FIFRA, no regulations or statutory source authorized the disclosure of data submitted in support of an applicant's labeling claims.\(^1\) Moreover, the Trade Secrets Act, 18 U.S.C. \(^1\) 1905, provided criminal penalties for unauthorized disclosure of trade secrets by federal officers or employees. At most, the above evidence establishes only a right of non-disclosure by the EPA. None of the federal provisions relied upon by Monsanto purport to create a federal entitlement in law to the data submitted pursuant to FIFRA. The Court finds that there was no federal property right in Monsanto's research.

The crux of Monsanto's property argument is that, as interpreted by the Eighth Circuit, Missouri has recognized a property right in defendant's data through its recognition of intellectual property expressed in the Restatement definition of trade secrets.<sup>2</sup> Sandlin v. Johnson, 141 F.2d 660 (8th Cir.

<sup>&</sup>lt;sup>1</sup> Nevertheless, it was not until the 1972 Amendments to FIFRA that provisions in FIFRA itself restricted the EPA's ability to consider one company's data in support of another company's application. See FF 22.

<sup>2 § 757</sup> provides:

One who discloses or uses another's trade secret, without a privilege to do so, is liable to the other if

<sup>(</sup>a) he discovered the secret by improper means, or

<sup>(</sup>b) his disclosure or use constitutes a breach of confidence reposed in him by the other in disclosing the secret to him, or

<sup>(</sup>c) he learned the secret from a third person with notice of the facts that it was a secret and that the third person discovered it by improper means or that the third person's disclosure of it was otherwise a breach of his duty to the other, or

<sup>(</sup>d) he learned the secret with notice of the facts that it was a secret and that its disclosure was made to him by mistake.

1944). Monsanto's trade secrets in the data it submitted is a separate and distinct specie of intellectual property than afforded protection by the patent laws. Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470 (1974). It is well settled that property rights are "created and their dimensions are refined by existing rules or understandings that stem from an independent source such as state law." Board of Regents v. Roth, 408 U.S. 564, 577 (1972).

Defendant does not controvert the fact that Monsanto enjoys certain property rights in its information, research and test data, however, it is defendant's position that none of these rights affect the federal government's consideration and disclosure of the data. The Court cannot agree with the EPA's characterization. The Restatement specifically prohibits disclosure of trade secrets without privilege. Internal use of Monsanto's data was never a stated risk inherent in submitting the data to EPA. While internal use by EPA does not literally involve disclosure of confidential data, it implicitly amounts, for all practical purposes, to disclosure of the data to Monsanto's competitors and the concomitant use of that data by Monsanto's competitors. The Court believes the Restatement's protection of trade secrets is intended to reach such constructive disclosure and use situations. See generally U.S. v. General Motors Corp., 323 U.S. 373 (1945) (Constitution protects every sort of interest the citizen may possess in his property). Therefore, the Court finds that Monsanto possessed a cognizable property right in the data submitted to EPA under § 3 pursuant to FIFRA.3 The property rights

<sup>&</sup>lt;sup>3</sup> It follows that if Monsanto had a property interest in preventing the internal use of its data by the EPA, then a property interest certainly attached in the non-disclosure of said data by the EPA. Both the Restatement, Trade Secrets Act, and prior agency prac-

Monsanto possesses in its intellectual property (data) are the rights to exclude others from the enjoyment of such data in particular, the right to prevent the unauthorized use and the right to prohibit disclosure of its data.

The next question is whether the EPA's consideration and disclosure of Monsanto's pre-1969 and post-1970 data causes an unconstitutional taking of plaintiff's property.

No set formula for determining what constitutes a taking has been articulated by the Supreme Court, however, the Court has stressed certain significant factors in what is essentially a factual inquiry: (1) nature of the invasion by the government; (2) economic impact on the owner's use of the property, particularly to the extent the regulation interferes with the distinct "investment backed" expectations; (3) public program or interest designed to benefit from the regulation. Penn Central Transportation Co. v. New York, 438 U.S. 104, 124-28 (1978); see U.S. v. Darby, 312 U.S. 100 (1941).

Section 3(c)(1)(D), which deals with agency use of Monsanto's data, does implicitly disclose plaintiff's data to its competitors. These competitors have not "contributed in money, services negotiations, skill, foresight or otherwise" to its creation. Thompson v. Consolidated Gas Utilities Corp., 300 U.S. 55, 78 (1937). In effect, the 1978 amendments to FIFRA give Monsanto's competitors a free ride at Monsanto's expense. The fundamental right of Monsanto and its property—the right to exclude—is appropriated by § 3(c)(1)(D). See Kaiser Aetna v. U.S., 444 U.S.

tice demonstrate that Monsanto could reasonably expect that its data would be kept confidential and would not enter the public domain.

164, 179-80 (1979). Moreover, the economic impact of § 3(c)(1)(D) is substantial and impairs Monsanto's "investment backed" expectations.

The Court also finds that  $\S 3(c)(1)(D)$  unabashedly operates to further a private purpose. Internal use of Monsanto's data can only enrich its competitors. The public stands little to gain from  $\S 3(c)(1)(D)$ . This is not a situation where competition is sparse or non-existent, to the contrary, the trial record amply demonstrates the competition and the pesticide industry as healthy and vibrant.

The Court is aware of the deference which must be shown Congressional pronouncements of what constitutes a public purpose. Berman v. Parker, 348 U.S. 26, 32 (1954). Nevertheless, the Court would be abdictating its responsibility to follow the Constitution if it did not rationally analyze laws which, in the name of public policy, mandate the forced sharing of property and markets created by one person for the benefit of private parties. Thompson, 300 U.S. at 78-79; U.S. v. Carolene Products, 304 U.S. 144, 147 (1938).

Section 3(c)(1)(D)'s interference with Monsanto's property is significant in comparison to the purported public good to be served. The EPA's internal use of Monsanto's property to support the registrations of Monsanto's competitors is not merely a change in the general law, but a destruction and therefore a taking of Monsanto's property.

Section 10 authorizes the public disclosure of test data and such matters as the effects of pesticides on human, plant and animal life. This information is initially scrutinized by the EPA (which has available to it all the scientific resources of the federal government and also of many private foundations and con-

sultants it may choose) to determine whether the submitted product is safe and effective. The presence of a registered product on the market is in itself evidence that the EPA has satisfied itself that the statutory objectives of FIFRA have been met. Furthermore, the product's label provides fair information as to what is being sold and fairly sets forth the nature, contents and purpose of the product.4 Therefore, the product's label provides the public with the assurance that the product is safe and effective and with the knowledge of the product's qualities. All that is accomplished by publicly disclosing the various data (property) submitted by Monsanto is to permit the public to share in the regulation of the pesticide industry. The cost of this "sharing" is that Monsanto's data is permanently committed to the public domain and thus effectively destroyed.

The Court cannot fairly say that Section 10's public disclosure provisions are a regulation of commerce. The public interest in seeing that safe and effective products are marketed is satisfied by the EPA's painstaking analysis of the complicated data submitted by Monsanto to register its products. The product's label effectively conveys the information the public needs to make an informed decision. Public disclosure of Monsanto's data by operation of § 10 is beyond Congress' regulatory powers and constitutes a taking of Monsanto's property. If Congress desires to exercise its power of eminent domain, which it has done in this case, and such power must be exercised

<sup>&</sup>lt;sup>4</sup> The Supreme Court's opinions in Corn Products Refining Co. v. Eddy, 249 U.S. 427 (1919) and National Fertilizer Association v. Bradley, 301 U.S. 178 (1937), which dealt with the constitutionality of the government's police power to require proper labeling, are inapposite because labeling is provided with the products and the EPA has already determined the products safe and effective.

in light of the due process protections afforded by the Fifth Amendment. Louisville Joint Stock Land Bank v. Radford, 295 U.S. 555, 589 (1935).

The next issue raised is whether the compulsory binding arbitration scheme envisioned by § 3(c)(1)(D)(ii) is adequate to compensate Monsanto for the property taken by operation of FIFRA. Under the arbitration scheme of § 3(c)(1)(D)(ii) Monsanto is forced to either conclude a compensation agreement with a "me-too" applicant or take its chances with binding arbitration. Monsanto's failure to either reach an agreement with a "me-too" applicant or to submit to arbitration forfeits Monsanto's right to compensation and its property.

The Court initially notes that judicial review of an arbitrator's decision (Federal Mediation and Conciliation Service) is all but denied in except a few cases involving fraud. Equally important is the absence of a formula of a guidance on the evaluation of data for

compensation purposes.

The Court finds the arbitration provision of § 3 arbitrary and vague. Not only are the arbitrators given no guidance as to the factors which make up just compensation, but judicial review of an arbitrator's decision, which may result in a confiscatory taking, is foreclosed. All of this is done without Monsanto's assent, see N.L.R.B. v. Jones & Laughlin Steel Corp., 301 U.S. 1, 45 (1937).

In the Court's view, the arbitration scheme does not afford Monsanto just compensation and constitutes a denial of due process in violation of the Fifth Amendment. See Baltimore & O.R.R. v. U.S., 298 U.S. 349, 357, 363, 368 (1936). The arbitration scheme also delegates judicial power to determine property rights disputes without the necessary prerequisites of Arti-

cle 3 of the Constitution. See U.S. v. Security Industrial Bank, 103 S.Ct. 407 (1982); Northern Pipeline Const. Co. v. Marathon Pipeline Co., 102 S.Ct. 2858 (1982).

The final issue presented is whether the Tucker Act is available to provide Monsanto with adequate compensation for the taking of Monsanto's property rights. The Court's initial inquiry focuses on "not whether the (challenged statute) expresses an affirmative showing of congressional intent to permit recourse to the Tucker Act remedy" but rather whether Congress has "withdrawn the Tucker Act grant of jurisdiction to the Court of Claims to hear a suit involving the (challenged statute) founded upon . . . the Constitution." Regional Rail Reorganization Cases, 419 U.S. 102, 126 (1974). In the Rail Act Cases, the court analyzed the relevant acts and determined the Tucker Act remedy was available. Crucial to the court's analysis was the court's belief that the money allocated under the Act to provide compensation was intended to satisfy the constitutional standard of just compensation.

A fair reading of FIFRA indicates that the "benefits" (compensation and exclusive use) afforded by § 3 were intended to be the sole compensation for any taking effectuated by §§ 3(c)(1)(D) and 10. The compensation scheme set up by FIFRA rests on the theory that since the date of the original submitter is utilized for the private benefit of a competitor—rather than the United States—then the competitor should pay the original data submitter. No monies were allocated by the government to insure that adequate compensation would occur. It is clear that this scheme purportedly acts to completely compensate Monsanto for property taken immediately by the de

facto exercise of eminent domain accomplished by operation of FIFRA. See Rail Cases, 419 U.S. at 149-50 (cautioning that it might be inconsistent to suppose that a Tucker Act suit would lie for the entire value, in cash, of rail properties).

The Court finds that the Tucker Act remedy is not available to Monsanto for the deprivation caused by §§ 3 and 10 of FIFRA. The case at bar concerns an immediate taking of Monsanto's property as of the passage of the amendments to FIFRA on September 30, 1978. The compensation scheme, as presently embodied in § 3(c)(1)(D)(ii) is vague and uncertain and in effect provides Monsanto with no compensation whatsoever. To suppose that Monsanto would have to endlessly petition the Court of Claims every time the EPA uses or discloses its property is contrary to the purposes of the Tucker Act which is intended to award a sum of money to remedy a wrong in whole and with finality. Moreover, the Court of Claims cannot provide the necessary declaratory and injunctive relief which Monsanto must have.

The Court is aware that its decision is contrary to that of a number of other federal courts. See e.g., Mobay Chemical Co. v. Costle, 519 F.Supp. 252 (W.D. Pa. 1981), aff'd sub nom Mobay Chemical Co. v. Gorsuch, 682 F.2d 419 (3rd Cir.), cert. denied 103 S.Ct. 343 (1982); Penwalt Corp. v. EPA, No. 80-2400 (E.D. Pa., July 17, 1981), aff'd Mobay, supra; Chevron Chemical Co. v. Costle, 499 F.Supp. 732 and 499 F.Supp. 755 (D. Del. 1980), aff'd 641 F.2d 104 (3rd Cir), cert. denied 452 U.S. 961 (1981); Petrolite Corp. v. EPA, 519 F.Supp. 966 (D.D.C. 1981). The Court deviates from these decisions because, in most of the above cited decisions, the courts summarily found that a property right did

not exist in data similar to that of Monsanto and, therefore, the courts necessarily did not analyze the 1978 amendments to FIFRA in their entirety. After reviewing the operation of FIFRA and its impact upon Monsanto's protected property rights, the Court is convinced that Congress exceeded its regulatory authority and violated the Fifth Amendment of the United States Constitution when in 1978 it amended §§ 3(c)(1)(D) and 3(c)(2)(A) and 10(b) and 10(d) of FIFRA.

Dated this 19th day of April, 1983.

/s/ H. Kenneth Wangelin H. KENNETH WANGELIN United States District Judge

## IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF MISSOURI EASTERN DIVISION

No. 79-366 C (1)

MONSANTO COMPANY, PLAINTIFF

vs.

ACTING ADMINISTRATOR, UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, DEFENDANT

[Filed Apr. 9, 1983]

## NUNC PRO TUNC ORDER

IT IS HEREBY ORDERED that page 39, lines 12 through 13 of the Court's Memorandum Opinion filed April 10, 1983 shall read as follows:

contrary, the trial record amply demonstrates that competition in the pesticide industry is healthy and vibrant.

Dated this 9th day of May, 1983.

/s/ H. Kenneth Wangelin H. KENNETH WANGELIN United States District Judge

#### APPENDIX B

## IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF MISSOURI EASTERN DIVISION

No. 79-366 C (1)

MONSANTO COMPANY, PLAINTIFF

vs.

ACTING ADMINISTRATOR, UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, DEFENDANT

[Filed Apr. 12, 1983]

### JUDGMENT

After a trial on the merits, wherein the Court carefully considered the evidence presented, the legal arguments proffered by the parties and the applicable law,

IT IS HEREBY ORDERED, ADJUDGED AND DECREED that §§ 3(c)(1)(D), 3(c)(2)(A), 10 (b) and 10(d) of the Federal Insecticide, Fungicide and Rodenticide Act, as amended by the Federal Pesticide Act of 1978, 7 U.S.C. § 136 et seq., are unconstitutional and unlawful and that they are beyond any power conferred by Congress by Article I, § 8, Clause 3 of the Constitution of the United States and are in violation of the Fifth Amendment thereto;

IT IS FURTHER ORDERED, ADJUDGED AND DECREED that defendant, his officers, agents, employees and representatives be and they are hereby

PERMANENTLY ENJOINED from the implementation and enforcement, in any manner, directly or indirectly, of §§ 3(c)(1)(D), 3(c)(2)(A), and 10(b) and 10(d) of the Federal Insecticide, Fungicide and Rodenticide Act, as amended by the Federal Pesticide Act of 1978; and

IT IS FURTHER ORDERED, ADJUDGED AND DECREED that § 3(c)(1)(D) of the Federal Insecticide, Fungicide and Rodenticide Act, as amended by the Federal Pesticide Act of 1978, does not authorize the defendant to use or consider in support of another's application for registration any of plaintiff's information, research and test data submitted prior to January 1, 1970, and such use and consideration thereof by defendant without plaintiff's express written permission is unlawful; and

IT IS FURTHER ORDERED, ADJUDGED AND DECREED that defendant, his officers, agents, employees and representatives be and they are hereby PERMANENTLY ENJOINED from any use or consideration for or disclosure to any other person of any of plaintiff's information, research and test data, whenever submitted to defendant or his predecessors, unless defendant shall have first obtained plaintiff's express written permission.

IT IS FURTHER ORDERED that a Memorandum Opinion detailing the findings of fact and conclusions of law in support of this Judgment shall issue within six (6) days of this Judgment.

Dated this 12th day of April, 1983.

/s/ H. Kenneth Wangelin H. KENNETH WANGELIN United States District Judge

#### APPENDIX C

## IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF MISSOURI EASTERN DIVISION

No. 79-366 C (1)

MONSANTO COMPANY, PLAINTIFF

vs.

ACTING ADMINISTRATOR, UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, DEFENDANT

[Filed May 9, 1983]

## AMENDED JUDGMENT

After a trial on the merits, the parties' filing of motions to stay and amend the Court's Judgment (which the Court treated as motions for a new trial),

IT IS HEREBY ORDERED, ADJUDGED AND DECREED that §3 (c) (1) (D), the last sentence of §3(c) (2) (a), §10(b) and §10(d) of the Federal Insecticide, Fungicide and Rodenticide Act, (hereinafter FIFRA) as amended by the Federal Pesticide Act of 1978, 7 U.S.C. §136 et seq., are unconstitutional and unlawful and that they are beyond any power conferred by Congress by Article I, §8, Clause 3 of the Constitution of the United States and are in violation of the Fifth Amendment thereto; and

IT IS HEREBY ORDERED, ADJUDGED AND DECREED that defendant, his officers, agents, employees and representatives be and they are hereby

PERMANENTLY ENJOINED from the implementation and enforcement, in any manner, directly or indirectly, of § 3(c)(1)(D), the last sentence of § 3(c)(2)(A), § 10(b) and § 10(d) of FIFRA, as amended by the Federal Pesticide Act of 1978; and

IT IS HEREBY ORDERED, ADJUDGED AND DECREED that §3(c)(1)(D) of FIFRA, as amended by the Federal Pesticide Act of 1978, does not authorize the defendant to use or consider in support of another's application for registration any of plaintiff's information, research and test data submitted prior to January 1, 1970, and such use and consideration thereof by defendant without plaintiff's express written permission is unlawful; and

IT IS HEREBY ORDERED, ADJUDGED AND DECREED that defendant, his officers, agents, employees and representatives be and they are hereby PERMANENTLY ENJOINED from any use or consideration for or disclosure to any other person, other than to representatives of other agencies or offices of the United States Government including the Committees or Houses of the United States Congress, of plaintiff's information, research and test data, whenever submitted to defendant or his predecessors, unless defendant shall have first obtained plaintiff's express written permission; and

IT IS HEREBY ORDERED, ADJUDGED AND DECREED that none of the aforesaid prevents the defendant from approving applications for pesticide registrations as permitted under §§ 3(c)(5) and 3(c)(7) of FIFRA in cases where the applicant has submitted to EPA, and relied solely upon, his own data to support his application for registration; provided that any applicant for registration must either

submit its own data, or cite its own previously submitted data, or cite data that appears in the public literature or cite the previously submitted data of another person with the prior written permission of such other person, and further that EPA is precluded from considering or using any other data in support of any application for registration.

Dated this 9th day of May, 1983.

/s/ H. Kenneth Wangelin H. KENNETH WANGELIN United States District Judge

#### APPENDIX D

## UNITED STATES DISTRICT COURT EASTERN DISTRICT OF MISSOURI EASTERN DIVISION

No. 79-0366-C (0) (Judge Wangelin)

MONSANTO COMPANY, PLAINTIFF

v.

LEE VERSTANDIG, Acting Administrator, United States Environmental Protection Agency, DEFENDANT

[Filed May 10, 1983]

# NOTICE OF APPEAL TO THE UNITED STATES SUPREME COURT

Notice is hereby given that defendant, the Acting Administrator of the United States Environmental Protection Agency, appeals to the United States Supreme Court from the final judgment entered in this action on April 12, 1983, as amended by the judgment entered on May 9, 1983. This appeal is taken pursuant to 28 U.S.C. §§ 1252, 2101.

Respectfully submitted,

ROSANNE MAYER
Attorney, Department of Justice
Environmental Defense Section
Ben Franklin Station
P.O. Box 7415
Washington, D.C. 20044

THOMAS E. DITTMEIER United States Attorney

/s/ Joseph B. Moore JOSEPH B. MOORE Assistant United States Attorney Room 414, 1114 Market Street St. Louis, Missouri 63101 314-425-4200, ext. 21

# CERTIFICATE OF SERVICE

Copy of the above and foregoing mailed to Kenneth Heineman, Coburn, Croft, One Mercantile Center, Suite 2900, St. Louis, Missouri, Gary Dyer, Lathrop Koontz, et al., 2600 Mutual Benefit Life Bldg., 2345 Grand Ave., Kansas City, MO 64108, and W. Wayne Withers, Monsanto Agricultural Products Co., 800 N. Lindbergh Blvd., St. Louis, MO 63166, this 10th day of May, 1983.

/s/ J. Moore

#### APPENDIX E

## CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

The Fifth Amendment to the Constitution provides in pertinent part:

No person shall be \* \* \* deprived of life, liberty, or property, without due process of law; nor shall private property be taken for public use, without just compensation.

The relevant provisions of the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. (& Supp. V) 136 et seq., as amended in 1978, provide:

## § 136a(c) Procedure for registration

(1) Statement required

Each applicant for registration of a pesticide shall file with the Administrator a statement which includes—

- (D) except as otherwise provided in subsection (c)(2)(D) of this section, if requested by the Administrator, a full description of the tests made and the results thereof upon which the claims are based, or alternatively a citation to data that appear in the public literature or that previously had been submitted to the Administrator and that the Administrator may consider in accordance with the following provisions:
  - (i) With respect to pesticides containing active ingredients that are initially registered under this subchapter after September 30, 1978, data submit-

ted to support the application for the original registration of the pesticide, or an application for an amendment adding any new use to the registration and that pertains solely to such new use, shall not, without the written permission of the original data submitted, be considered by the Administrator to support an application by another person during a period of ten years following the date the Administrator first registers the pesticide: *Provided*, That such permission shall not be required in the case of defensive data;

(ii) except as otherwise provided in subparagraph (D)(i) of this paragraph, with respect to data submitted after December 31, 1969, by an applicant or registrant to support an application for registration, experimental use permit, or amendment adding a new use to an existing registration, to support or maintain in effect an existing registration, or for reregistration, the Administrator may, without the permission of the original data submitter. consider any such item of data in support of an application by any other person (hereinafter in this subparagraph referred to as the "applicant") within the fifteen-year period following the date the data were originally submitted only if the applicant has made an offer to compensate the original data submitter and submitted such offer to the Administrator accompanied by evidence of

delivery to the original data submitter of the offer. The terms and amount of compensation may be fixed by agreement between the original data submitter and the applicant, or, failing such agreement, binding arbitration under this subparagraph. If, at the end of ninety days after the date of delivery to the original data submitter of the offer to compensate, the original data submitter and the applicant have neither agreed on the amount and terms of compensation nor on a procedure for reaching an agreement on the amount and terms of compensation, either person may initiate binding arbitration proceedings by requesting the Federal Mediation and Conciliation Service to appoint an arbitrator from the roster of arbitrators maintained by such Service. The procedure and rules of the Service shall be applicable to the selection of such arbitrator and to such arbitration proceedings, and the findings and determination of the arbitrator shall be final and conclusive, and no official or court of the United States shall have power or jurisdiction to reveiw any such findings and determination, except for fraud, misrepresentation, or other misconduct by one of the parties to the arbitration or the arbitrator where there is a verified complaint with supporting affidavits attesting to specific instances of such fraud, misrepresentation, or other misconduct. The

parties to the arbitration shall share equally in the payment of the fee and expenses of the arbitrator. If the Administrator determines that an original data submitter has failed to participate in a procedure for reaching an agreement or in an arbitration proceeding equired by this subparagraph, or falled to comply with the terms of an agreement or arbitration decision concerning compensation under this subparagraph, the original data submitter shall forfeit the right to compensation for the use of the data in support of the application. Notwithstanding any other provision of this subchapter, if the Administrator determines that an applicant has failed to participate in a procedure for reaching an agreement or in an arbitration proceeding as required by this subparagraph, or failed to comply with the terms of an agreement or arbitration decision concerning compensation under this subparagraph, the Administrator shall deny the application or cancel the registration of the pesticide in support of which the data were used without further hearing. Before the Administrator takes action under either of the preceding two sentences, the Administrator shall furnish to the affected person, by certified mail. notice of intent to take action and allow fifteen days from the date of delivery of the notice for the affected person to

respond. If a registration is denied or cancelled under this subparagraph, the Administrator may make such order as the Administrator deems appropriate concerning the continued sale and use of existing stocks of such pesticide. Registration action by the Administrator shall not be delayed pending the fix-

ing of compensation;

(iii) after expiration of any period of exclusive use and any period for which compensation is required for the use of an item of data under subparagraphs (D)(i) and (D)(ii) of this paragraph, the Administrator may consider such item of data in support of an application by any other applicant without the permission of the original data submitter and without an offer having been received to compensate the original data submitter for the use of such item of data;

- (E) the complete formula of the pesticide; and
- (F) a request that the pesticide be classified for general use, for restricted use, or for both.

(2) (A) Data in support of registration

The Administrator shall publish guidelines specifying the kinds of information which will be required to support the registration of a pesticide and shall revise such guidelines from time to time. If thereafter he requires any additional kind of information under subparagraph (B) of this paragraph, he shall permit sufficient time

for applicants to obtain such additional information. The Administrator, in establishing standards for data requirements for the registration of pesticides with respect to minor uses, shall make such standards commensurate with the anticipated extent of use, pattern of use, and the level and degree of potential exposure of man and the environment to the pesticide. In the development of these standards, the Administrator shall consider the economic factors of potential national volume of use, extent of distribution, and the impact of the cost of meeting the requirements on the incentives for any potential registrant to undertake the development of the required data. Except as provided by section 136h of this title, within 30 days after the Administrator registers a pesticide under this subchapter he shall make available to the public the data called for in the registration statement together with such other scientific information as he deems relevant to his decision.

§ 136h. Protection of trade secrets and other information

## (b) Disclosure

Notwithstanding any other provision of this subchapter and subject to the limitations in subsections (d) and (e) of this section, the Administrator shall not make public information which in his judgment contains or relates to trade secrets or commercial or financial information obtained from a person and privileged or confidential, except that, when necessary to carry out the provisions of this subchapter, information relating to formulas of products acquired by authorization of this subchapter may be revealed to any Federal agency consulted and may be revealed at a public hearing or in findings of fact issued by the Administrator.

## (d) Limitations

- (1) All information concerning the objectives, methodology, results, or significance of any test or experiment performed on or with a registered or previously registered pesticide or its separate ingredients, impurities, or degradation products, and any information concerning the effects of such pesticide on any organism or the behavior of such pesticide in the environment, including, but not limited to, data on safety to fish and wildlife, humans and other mammals, plants, animals, and soil, and studies on persistence, translocation and fate in the environment, and metabolism, shall be available for disclosure to the public: Provided. That the use of such data for any registration purpose shall be governed by section 136a of this title: Provided further, That this paragraph does not authorize the disclosure of any information that-
  - (A) discloses manufacturing or quality control processes.
  - (B) discloses the details of any methods for testing, detecting, or measuring the quantity of any deliberately added inert ingredient of a pesticide, or
  - (C) discloses the identity or percentage quantity of any deliberately added inert ingredient of a pesticide.

unless the Administrator has first determined that disclosure is necessary to protect against an unreasonable risk of injury to health or the environment.

- (2) Information concerning production, distribution, sale, or inventories of a pesticide that is otherwise entitled to confidential treatment under subsection (b) of this section may be publicly disclosed in connection with a public proceeding to determine whether a pesticide, or any ingredient of a pesticide, causes unreasonable adverse effects on health or the environment, if the Administrator determines that such disclosure is necessary in the public interest.
- (3) If the Administrator proposes to disclose information described in clause (A), (B), or (C) of paragraph (1) or in paragraph (2) of this subsection, the Administrator shall notify by certified mail the submitter of such information of the intent to release such information. The Administrator may not release such information, without the submitter's consent, until thirty days after the submitter has been furnished such notice: Provided, That where the Administrator finds that disclosure of information described in clause (A), (B), or (C) of paragraph (1) of this subsection is necessary to avoid or lessen an imminent and substantial risk of injury to the public health, the Administrator may set such shorter period of notice (but not less than ten days) and such method of notice as the Administrator finds appropriate. During such period the data submitter may institute an action in an appropriate district court to enjoin or limit the proposed disclosure. The court shall give expedited consideration to any such action. The court may obtain disclosure, or limit the disclosure or the parties to whom disclosure shall be made, to the extent that-
  - (A) in the case of information described in clause (A), (B), or (C) of paragraph (1) of this subsection, the proposed disclosure is not re-

quired to protect against an unreasonable risk of injury to health of the environment; or

(B) in the case of information described in paragraph (2) of this subsection, the public interest in availability of the information in the public proceeding does not outweigh the interests in preserving the confidentiality of the information.

## (e) Disclosure to contractors

Information otherwise protected from disclosure to the public under subsection (b) of this section may be disclosed to contractors with the United States and employees of such contractors if, in the opinion of the Administrator, such disclosure is necessary for the satisfactory performance by the contractor of a contract with the United States for the performance of work in connection with this subchapter and under such conditions as the Administrator may specify. The Administrator shall require as a condition to the disclosure of information under this subsection that the person receiving it take such security precautions respecting the information as the Administrator shall by regulation prescribe.

## (f) Penalty for disclosure by federal employees

(1) Any officer or employee of the United States or former officer or employee of the United States who, by virtue of such employment or official position, has obtained possession of, or has access to, material the disclosure of which is prohibited by subsection (b) of this section, and who, knowing that disclosure of such material is prohibited by such subsection, willfully discloses the material in any manner to any person not entitled to receive it, shall be fined not more than \$10,000 or imprisoned for

not more than one year, or both. Section 1905 of title 18 shall not apply with respect to the publishing, divulging, disclosure, or making known of, or making available, information reported or otherwise obtained under this subchapter. Nothing in this subchapter shall preempt any civil remedy under State or Federal law for wrongful disclosure of trade secrets.

- (2) For the purposes of this section, any contractor with the United States who is furnished information as authorized by subsection (e) of this section, or any employee of any such contractor, shall be considered to be an employee of the United States.
- (g) Disclosure to foreign and multinational pesticide producers
- (1) The Administrator shall not knowingly disclose information submitted by an applicant or registrant under this subchapter to any employee or agent of any business or other entity engaged in the production, sale, or distribution of pesticides in countries other than the United States or in addition to the United States or to any other person who intends to deliver such data to such foreign or multinational business or entity unless the applicant or registrant has consented to such disclosure. The Administrator shall require an affirmation from any person who intends to inspect data that such person does not seek access to the data for purposes of delivering it or offering it for sale to any such business or entity or its agents or employees and will not purposefully deliver or negligently cause the data to be delivered to such business or entity or its agents or employees. Notwithstanding any other provision of this subsection, the Administrator may disclose information to any person in connection with a public proceeding under law or regulation, subject to restrictions on

the availability of information contained elsewhere in this subchapter, which information is relevant to a determination by the Administrator with respect to whether a pesticide, or any ingredient of a pesticide, causes unreasonable adverse effects on health or the environment.

(2) The Administrator shall maintain records of the names of persons to whom data are disclosed under this subsection and the persons or organizations they represent and shall inform the applicant or registrant of the names and affiliations of such persons.

(3) Section 1001 of title 18 shall apply to any affirmation made under paragraph (1) of this subsection.

Office-Supreme Court, U.S. F I L E D

DEC 21 1983

ALEXANDER L STEVAS,

# In the Supreme Court of the United States

OCTOBER TERM, 1983

WILLIAM D. RUCKELSHAUS, ADMINISTRATOR, UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, APPELLANT

U.

#### MONSANTO COMPANY

ON APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF MISSOURI

## JOINT APPENDIX

#### REX E. LEE,

Solicitor General, Department of Justice, Washington, D.C. 20530. (202) 633-2217 Counsel for Appellant.

#### A. RAYMOND RANDOLPH.

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JURISDICTIONAL STATEMENT FILED AUGUST 5, 1983 PROBABLE JURISDICTION NOTED OCTOBER 11, 1983

# In the Supreme Court of the United States

OCTOBER TERM, 1983

No. 83-196

WILLIAM D. RUCKELSHAUS, ADMINISTRATOR, UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, APPELLANT

U

### MONSANTO COMPANY

ON APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF MISSOURI

## JOINT APPENDIX

## TABLE OF CONTENTS\*

	Page
District Court Docket Entries	1
First Amended Complaint for Declaratory Judgment, In-	
junctive and other Equitable Relief	15
Defendant's Answer	29
First Supplemental Stipulation of Facts	35
Monsanto's Proposed Findings of Facts	38
Plaintiff's Exhibit 41 (Testimony of George G. Rohwer	-
from Mobay Chemical Corp. v. Costle, W. D. Pa., C. A.	
No. 79-591)	60
Plaintiff's Exhibit 44 (Deposition of Cipriano Cueto, Jr.	-00
from Dow Chemical Co. v. Costle, E. D. Mich., C. A. No.	
76–10087)	63
Defendant's Exhibit P (Letter from H. Alford to B. Car-	00
ceau)	ce
COM/ ************************************	00

Defendant's Exhibit Q (Letter from T. E. Adamczyk to J. Hattori)
Defendant's Exhibit R (Letter from J. E. Adamczyk to J. Walker)
Defendant's Exhibit S (Letter from T. E. Adamczyk to J. J. Lenzotti)
Defendant's Exhibit T (Letter from T. E. Adamczyk to J. E. Gee)
Defendant's Exhibit HH (Minutes of Board of Directors, National Agricultural Chemicals Association, April 25, 1979)
Defendant's Exhibit PP (Affirmation of Multinational Status)
Defendant's Exhibit CCC (Deposition of Dexter B. Sharp).
Defendant's Exhibit DDD (Deposition of Jack Dent Early)
Defendant's Exhibit FFF (Deposition of Harry W. Hays in <i>Dow Chemical Co.</i> v. Costle, E. D. Mich., C. A. No. 76-10087)
Defendant's Exhibit GGG (Deposition of Cleve A. I. Goring in <i>Dow Chemical Co. v. Costle</i> , E. D. Mich., C. A. No. 76-10087)
Defendant's Exhibit III (Testimony of Harry W. Hays in Mobay Chemical Corp. v. Costle, W. D. Pa., C. A. No. 79-591
Defendant's Exhibit KKK (Testimony of Harold Alford in Mobay Chemical Corp. v. Costle, W. D. Pa., C. A. No. 79-591)
Defendant's Exhibit VVV (Deposition of Nicholas Lee Reding)
Excerpts from Trial Transcript
Plaintiff's Exhibit 6 (Pesticide Development Chart)
Order Noting Probable Jurisdiction

<sup>\*</sup>The opinion of the district court appears in the appendix to the jurisdictional statement and has not been reproduced.

## WILLIAM RUCKELSHAUS, ADMINISTRATOR OF ENVIRONMENTAL PROTECTION AGENCY, DEFENDANT

U.

#### MONSANTO COMPANY, PLAINTIFF

#### CAUSE

7 USC 135-136 et seq, 5 USC 551 et seq, 28 USC 2201 and 2202. Suit to declare illegal and enjoin implementation of Federal Pesticide Act of 1978, amending Sections 3(c)(1)(D), 3(c)(2)(s) and 10 of 7 USC 135-136 et seq. (FIFR Act)

#### ATTORNEYS

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### 79-0366C(1) Monsanto v. Costle, et al

Date .	Proceedings
1979	
Mar. 30	Complaint for declaratory judgment, injunctive and other equita- ble relief; application for preliminary injunction, suggestions in support of application—Fld. Summons Issued (60 Days).
Apr. 10	Marshal's return (summons)—Fld. Served on U.S. Atty, by serving Kathy Hempin 4/2/79.
May 4	Proposed stipulation of facts—Fid. by Pitff. Under seal pursuant to Protective Order of Court. Approved (HKW).

Date	Proceedings
May 4	. Motion for protective order; with proposed order; suggestions in support; stipulation; joint motion for entry of pretrial order; with proposed pretrial order, suggestions in support—Fld. by Pitff. Fld. by Both.
May 4	Pretrial order (HKW)—Fld.
May 4	Order (HKW) (protective order)—Fld. Re: Proposed Stipulation of Facts fld. 5/4/79.
May 31	<ul> <li>First amended compliant for declaratory judgment, injunctive and other equitable relief—Fld. by Pltff.</li> </ul>
June 1	additional findings of fact to be within scope of protective order of May 4, 1979—Memo for clerk fld. by Deft. Leave granted (HKW). Deft's Findings put under seal.
June 4	Request until June 18, 1979 to file response to proposed findings of pretrial order—Memo for Clerk fld. by Pltff. Leave Granted (HKW). CC: Attys.
June 7	Request until May 25, 1979 to file response to proposed findings of fact—Memo for clerk fld. So Ordered (HKW).
	Request to July 2, 1979 to file response to proposed findings of fact of pretrial order—Memo for Clerk fld. by Pltff. Leave Granted (HKW) CC: Atty.
July 2	Response to proposed additional findings of fact-Fld. by Pltff.
July 9	Response to proposed findings of fact—Fld. by Pltff. and Placed under Seal. Entire file placed in Vault.
July 27	Proposed amendment of pre-trial order—fld by pltff.  Answer—Fld.
	Pretrial conference reset for September 10, 1979—Memo for Clerk fld. by Pltff. Leave Granted (HKW) CC: Atty.
Aug. 31	Proposed additional findings of fact (pages 36-55)—Fld. by Deft. Previous date of pretrial conference vacated. Reset on October 29, 1979—Memo for Clerk Fld. by Pltff. Leave Granted (HKW) CC: Attys.
	Request leave to withdraw proposed additional findings fld. 8/30/79 and to replace with correct proposed additional findings of fact—Memo for Clerk fld. by Deft. Leave Granted (HKW).
Oct. 29	W. Wayne Withers enters appearance as co-counsel for pltff— Memo for Clerk fld. by Pltff.
	Pre-trial conference had.
Nov. 1	Stipulation; Stipulation of facts; joint statement of proposed findings of fact as to which the parties do not agree—Fld. by Pltff. and Deft.
Dec 17	First list of witnesses—Fld. by Pltff.
Dec. 17	Second pre-trial order—Fld. by Pltff. and Deft. So Ordered (HKW).
1980	
Mar. 4	Notice to take deposition—Herbert S. Harrison—4/1/80; Douglas B. Campt—4/2/80; Richard F. Mountford and James L. Skaptason—4/3/80; Thomas E. Adamczyk—4/4/80, fld. by Pltff.
June 20	Notice of Deposition of Dr. Jack Early on 7/2/80 by deft. w/ attached Exhibit A.

Date	Proceedings
July 16	Motion for summary judgment w/Memorandum in Support; and Attachments A thru K, and attached proposed Order, fld. by defts. (Ref. 12/29/81).
July 28	Request for Hearing, fld. by deft. 8/13/80 Motion of defts. for Summary Judgment fld. on 7/16/80 submitted to Judge Wangelin.
Sept. 2	Deposition of Jack Dent Early taken on behalf of deft. (1 Vol.) fld.
Sept. 8	Memorandum in Opposition to defts. Motion for Summary Judg- ment, fld. by pltf. Leave to File granted (HKW) (Documents and sealed and not to be opened except by the order of this Court- HKW) placed in Vault.
Sept 17	First Supplemental Stipulation of Facts fld.
	Trial Setting—Order of Court Relating to Trial; Case set for Non- Jury Trial on January 12, 1981, fld. CC: Attys. By Court.
	Motion for a Viewing of Its Premises, fld. by pltff. Monsanto Co. w/Suggestions in Support, fld. (REF. 2/25/81).
	Pre-Trial: List of Witnesses; Designation of Exhibits; fld. by deft.
Nov. 24	Pre-Trial: List of Witnesses; Exhibit List, fld. by pltf. 12/1/80 Pltffs. Motion for a Viewing of Premises fld. on 11/13/80,
Don 4	Submitted to Judge Wangelin.
Dec. 4	Motion for extension of time to respond to pltf. Motion for Viewing of Premises, w/attached Proposed Order, fld. by deft. (REF 12/4/80).
Dec. 4	Motion for Extension of Time until 12/9/80 to respond to pltfs. Motion fld. 12/4/80, Leave Granted (HKW).
Dec. 10	Stipulation (HKW)—Stipulated and agreed to by and between the parties that Para. 2 of Stipulation entered into on 5/4/79 is hereby amended. Approved (HKW); Second Supplemental Stipulation of Facts, fld.; Third Pre-Trial Order, fld. So Ordered (HKW).
Dec. 15	Memorandum in Opposition to pltffs. Motion for A Viewing of its Premises, fld by deft.
Dec. 24	Reply Suggestions in Support of Motion for a Viewing of Its Premises, Fld by Pltf.
1981	
Jan. 8	Motion for Summary Judgment heard.
Feb. 25	Motion Fld. 11/13/80 by Pltff, Denied at this time (HKW).
Mar. 26	Notice of Termination of Stipulation, by Deft., Fld.
Mar. 26	Motion for Leave to File Supplemental Memorandum, by Deft, fld. w/"Proposed" Suppl. Memorandum in Support of Deft's Motion for Summary Judgment (Ref 3/27/81).
Mar. 27	Motion for Leave to File Suppl. Memo, Granted (HKW) (cc:parties).
Mar. 27	Supplemental Memoranum in Support of Deft's Motion for Summary Judgment, with Attachments, Fld. by Defts.
Apr. 7	Minute entry; Pre-Trial Conference had.
Apr. 7	Pre-Trial Order No. IV; pltff. shall file motion for summary judgment by 5/7/81 and deft. shall respond by 6/23/81; pltff. shall respond to deft's response by 7/7/81. (HKW) cc: all parties.
Apr. 17	Reply to Deft's Suppl. Memo in Support of his Motion for Sum-
	mary Judgment, by Pltff, fld.

Date	Proceedings
May 7	Plff's Cross-Motion for Summary Judgment and Attachments, with brief in support, fld. (REF: 12/29/81).
May 8	
May 19	Extension of Time granted to Wednesday, May 27, 1981, within to reply to Deft.'s Motion for Reconsideration of Pre-Trial Order NO. IV. Memo by Pltff. fld. Leave Granted (HKW).
May 27	81—Motion of Deft. For Reconsideration, with memo in support fld. 5/8/81, submitted to Judge Wangelin.
June 19	Motion For Extension of Time, by Deft. fld. So Ordered (HKW) (cc: parties) Until July 10, 1981, to comply with paragraphs 3, 4, and 5 Pretrial Order No. IV and Until July 21, 1981, to comply with paragraph 6 of that order. (Motion fld. with attachments).
July 27	Findings of Material Facts. Leave to File Granted (HKW).
July 27	Response To Pltff's Proposed Finding of Material Facts, by Deft. fld. (with Attachments).
July 27	<ul> <li>Memorandum In Opposition To Monsanto's Cross-Motion For Summary Judgment, by Deft. fld. with attachments).</li> </ul>
Aug. 5	Motion For Extension of Time, by Pltff fld. (REF: 8-5-81).
	<ul> <li>Order (HKW)—It is hereby ordered that Pltff is grated to and including September 11, 1981, within which to comply with Paragraph 7 of Pre-Trial Order No. IV. (cc: parties).</li> </ul>
Aug. 28	Motion For Protective Order, Suggestion In Support Thereof, by Pltff fld.
Aug. 28	Order (HKW)—It is Hereby Ordered that the deposition of Dr. Dexter B. Sharp shall be maintained in a sealed envelope; It is Further Ordered that said deposition shall not be disclosed to anyone by Deft. or her counsel and only used by Deft. and her counsel for the purpose of preparation of this action. (cc: parties).
Sept. 11	Reply To Deft's Memorandum In Opposition To Pltff's Cross- Motion For Summary Judgment, by Pltff fld.
Sept. 11	Reply To Deft's Response To Pltff's Proposed Findings of Material Fact and Pltff's Request For Evidentiary Hearing, by Pltff fld. 9/15/81—Cross-Motion for summary judgment fld. by pltff on 5/
Sept. 29	7/81 w/Responses submitted to Judge Wangelin. Order (HKW)—It is Hereby Ordered that Deft. Anne B. Gorsuch's motion for reconsideration be and is Denied. (cc: parties).
Oct. 5	
Dec. 4	Pursuant to Honorable H. Kenneth Wangelin's instruction, Cause Set For Non-Jury Trial on Monday, December 28, 1981 at 10:00 a.m. (cc: parties).
Dec. 8	Pursuant to Judge Wangelin's Instructions, Non-Jury Trial Setting of December 28, 1981 Is Vacated. Cause Is Passed To Further Order.

Date	Proceedings
Dec 29	Memorandum and Order (HKW)—It is Hereby Ordered that Pitff's motion for summary judgment be and is Denied; and it is Further Ordered that Deft's motion for summary judgment be and is Denied. (cc: parties).
1982	
Jan. 13	Cause Set for Non-Jury Trial on March 8, 1982.—The Order of Court Relating to Trial is attached herewith. (cc: parties by letter of Court).
Feb. 26	Witness List, Exhibit List and Deposition List, by Deft. fld.
Feb. 26	Pretrial Compliance and Certificate of Service, by Pltff. fld. (List of Witnesses, Proposed Depositions (and previous trial testimony to be offered in evidence), Exhibit List).
	Statement of Objections To Pltf's Exhibits, by Deft. fld. Objections To Deft's Exhibits, by Pltff. fld.
	Non-Jury Trial (1st Day)—Parties present for trial. Pltff. evidence commenced but not concluded. Proceedings postponed until tomorrow at 10:00 a.m. Ordered that transcript be suppressed and sealed.
Mar. 8	Deposition of Will D. Carpenter, Ph.D., taken on behalf of the Deft., fld.
Mar. 9	Deposition of Dexter B. Sharp. Ph.D., taken on behalf of the Deft.,
Mar. 9	Deposition of Nicholas Lee Reding, taken on behalf of the Deft., fld.
Mar. 9	Deposition of Fred Warren Slife, Ph.D., taken on behalf of the Deft., fld.
Mar. 9	Non-Jury Trial (2nd Day)—Parties present. Pltff. evidence resumed but not concluded. Proceedings postponed until tomorrow at 10:00.
Mar. 10	Non-Jury Trial (3rd Day)—Parties present. Pltff. evidence resumed and concluded. Oral motions of Pltff. & Deft. for directed verdict at close of Pltff's case made, and denied. Pltff. & Deft. granted leave to file written motion. Deft. evidence commenced but not concluded. Proceedings postponed until tomorrow at 10:00.
Mar. 11	Non-Jury Trial (4th Day)—Parties present. Deft. evidence resumed but not concluded. Proceedings postponed until tomorow at 10:00 a.m.
Mar. 12	Non-Jury Trial (5th Day)—Parties present. Deft. evidence resumed and concluded. Pltff. granted 30 days to file brief; Deft. granted 30 days to respond; Pltff. granted 5 days to reply at which time cause will be taken under submission. Briefing schedule to commence upon receipt of transcript. Record will remain open
Mar. 19	for 7 days. If Pltff. file earlier time will start at this time.  Designation of Deposition and Prior Trial Testimony To Be Of-
	fered by Deft. As Evidence, by Deft. Anne M. Gorsuch fld.
Mar. 31	Letter to Mr. Shrybman regarding the return of seven envelopes, together with microfiche that was all received by Monsanto.
Apr. 21	Copy of letter that was sent to Judge Wangelin without the
	heading reference to the Monsanto docket, fld.

Date	Proceedings
May 25	Motion For Order to Show Cause Why Deft., Anne M. Gorsuch, Administrator, Evironmental Protection Agency, Should not Be Held In Contempt of This Court and For An Order Directing Deft. To Deposit Certain Documents With This Court and For Such Other Orders Appropriate Under The Circumstances, Suggestions In Support Thereof, by Pltff. fld. (8-31-82).
May 25	Order (HKW) It is Hereby Ordered that Deft. Anne M. Gorsuch, appear at a hearing to be held the 14th of June, 1982, in Room 1 of the U.S. Courthouse, St. Louis, MO, and show cause why she should not be held in contempt for violating this Court's Order of April 7, 1981;
	It is Further Ordered that Deft., Anne M. Gorsuch, immediately and forthwith obtain from Clausen Ely, Jr. all documents disclosed and transmitted to Mr. Ely regarding glyphosate, along with all copies of said documents which Mr. Ely may have made or directed be made, along with all notes and memoranda which may have been prepared by Mr. Ely or others acting with him relating to such documents, and that deft. obtain from Mr. Ely and all parties to whom the documents or copies were disclosed, a written affirmation that all such copies have been delivered to deft. and that no further use will be made of said documents it is further ordered that all documents so obtained by deft. shall immediately and forthwith be deposited with this Court pending
May 25	the hearing on the Order to Show Cause, on the 14th of June, 1982. (cc: parties).  For Post Trial Discovery, Suggestions In Support Thereof, by Pltff.
May 25	fld. Order (HKW)—It Is Hereby Ordered, on the Motion of Pltff. Monsanto Co., and for good cause shown that pltff. be allowed to conduct post-trial discovery in this cause for the purpose of preparation for the hearing on the 14th day of June, 1982, on the Order to Show Cause. (cc: parties)
May 26	Notice To Take Deposition of Therese Murtagh, by Pltff fld.
May 26	Notice to Take Deposition of Timothy Thomas by Pltff. fld.
	Notice to Take Deposition of Clausen Ely, Jr., by Pltff. fld.  Motion For An Order Directing Clausen Ely, Jr. To Provide the Identity of All Persons To Whom Disclosure of Pltff's data Has Been Made w/Suggestions In Support Thereof, by Pltff. fld. (REF: 6-7-8).
June 7	Order (HKOW)—It Is Hereby Ordered, Adjudged and Decreed that Mr. Clausen Ely, Jr. shall immediately and forthwith furnish a written affirmation to Pltff. deft. and this Court setting out the
	identity of any and all persons and the identity of any entity or entities employing such persons or on whose behalf each such person was acting to which the documents, copies thereof, or any information contained therein were disclosed by Mr. Ely or anyone acting on his behalf. (cc: parties).
June 14	Letter regarding response to Order of 6/7/8 fld by Clausen Ely, Jr.
June 25	Deposition of Clausen Ely, Jr. taken on behalf of the Pltff., fld.
June 25	Deposition of Timothy Thomas, taken on behalf of the Pltff. fld.

Date	Proceedings
June 25	Deposition of Therese Murtagh (2 Volumes), taken on behalf of the Pltff. fld.
June 25	Exhibits fld. pertaining to the three (3) depositions fld. on this date.
June 30	Copies of a decision entered on June 22, 1982 by the Third Circuit Court in the consolidate appeals Mobay Chemical Corp. v. Anne M. Gorsuch, Nos. 81-2190/2191 (3rd Cir.), and Pennwalt Corp. v.
,	Anne M. Gorsuch, No. 81-2469 (3rd Cir.) fld.
July 13	Transcript of 'Trial, fld.
Aug. 12	Post-Trial brief, by Pltff. fld.
Aug. 12	Proposed Conclusions of Law, by Pltff. fld.
Aug. 12	Proposed Findings of Facts, by Pltff. fld.
Aug. 31	Withdrawal of Motion To Show Cause and Motion To Vacate Order To Show Cause, by Pltffd. fld.
Aug 31	Order (HKW)—Upon withdrawal of Motion to Show Cause by Monsanto and for good cause shown, this Court's May 25, 1982 Order that deft. Anne M. Gorsuch show cause why she should not be held in contempt for violating this Court's Order of April 7, 1981 is HEREBY VACATED. (cc: Parties)
Aug. 31	Order (HKW)-This Court Hereby Ordered That:
	I. Deft. Shall comply with the following procedures prior to any release of documents (including any written, recorded, transcribed, punched, taped, filmed or graphic matter of any kind or description, however produced or reproduced) in the possession of the Agency which although not themselves submitted by Monsanto Co., are determined to contain or discuss data submitted by Monsanto in support of its pesti- cide registrations.
	A. Prior to release of any such documents, the Agency shall prepare the documents in the exact form in which disclosure is proposed, including any deletions to the documents.
	B. A copy of the proposed disclosure shall be provided to Monsanto's company counsel at 800 North Lindbergh Blvd., St. Louis, Mo, by certified mail and a duplicate copy made available to Monsanto's Washington office at the same time.
	C. If Monsanto informs the Agency of objection to any portion of the disclosure within ten business days of certified return receipt of the proposed disclosure, the Agency shall provide Monsanto's Company counsel by certified mail a copy of the Agency's final proposal for release incorporating its response to the objections raised by Monsanto and shall make a duplicate copy available to Monsanto's Washington office at the same

Date	Proceedings
	D. If Monsanto informs the Agency of contained objections to any portion of the disclosure within five business days of receipt by Monsanto's company counsel of this notice, the Agency shall provide Monsanto's company counsel with a final notice of its intent to release the objectionable document(s) at least thirty days prior to release of the document(s). A duplicate copy shall be made available to Monsanto's Washington office at the same time.
, • )	II. Nothing in this Order shall be construed to restrict EPA's publication or public release in connection with its official duties of materials which have been expressly prepared to be publicly available for official reasons unrelated to the requirements of Sections 3(c)(2)(A) and 10 of FIFRA or of the
	Freedom of Information Act. Examples of such materials include preambles to tolerance regulations, technical support documents associated with registration standards or other regulatory actions, and similar documents.  III. This relief is granted without prejudice to Monsanto's
	right to request the same or related relief as part of the final judgment in this case. IV. This Order does not replace or modify any provisions of Pretrial Order IV previously entered in this case. (cc: par-
Aug. 31	ties).  Judgment (HKW)—It is Hereby Ordered, Adjudged and Decreed That:
	<ol> <li>The Administrator of the Environmental Protection Agency shall establish procedures to accomplish the following:         <ol> <li>Upon entry of this Judgment and return of the herein described documents by this Court, the Administrator shall maintain in a secured damageproof repository the actual documents obtained by Deft. and submitted to this Court and the additional documents identified by the parties with the parties' joint motion as possible subjects of the disclosure (hereafter "disclosed docu- ments").</li> </ol> </li> </ol>
	(2) The Administrator shall identify all applications for registrations of pesticide products received after May 7, 1982 which contain glyphosate (N-phosphonomethylgly- cine); or any N-oxide of N-carboxymethyl glyphosate; or any salts, esters, amides, thioacids, thioesters, acid chlorides or combinations thereof, of N-phosphonometh- ylglycine or of any N-oxide of N-carboxymethyl glypho- sate (hereafter "covered application").
	(3) For each "covered application, the Administrator shall determine whether supporting data is submitted in any of the following subject areas: Toxicology, Residue and metabolism, Environmental fate in soil."

Date

Proceedings

- (4) For each covered application, the Administrator shall submit the confidential statement(s) of formula and any supporting data in the above identified subject areas to the Scientific Advisory Panel (hereafter "SAP or Panel") established pursuant to 25(d) of FIFRA together with the actual disclosed documents identified in item 1 above.
- (5) the Administrator shall provide instructions to the Panel that it review the materials submitted to it in order to determine whether the materials submitted with the covered applications have been developed independently of the disclosed information. EPA shall provide to the Panel copies of the unexpurgated originals from which the disclosed documents were prepared. The applicant or Monsanto may make presentations to the Panel and answer any inquiries put by the Panel, but neither may have access to the other's data or formula information without the other's consent. The Panel may also request any additional information from EPA which it deems appropriate. All deliberations of the Panel shall be in executive session.
- II. If a majority of the SAP determines that the materials in the covered application contain only information that was developed independently of the information contained in the disclosure documents, the Administrator shall certify that the covered application is formally accepted for review by the Agency unless he finds that the SAP did not have substantial information before it to support its finding. If a majority finds that any materials in the covered application were not developed independently of the information contained in the disclosed documents, the Administrator shall deny the application unless he finds that the SAP did not have substantial information before it to support its finding. If no majority of the SAP can make either finding, the SAP shall submit a written report of its conclusions, including those of individual members, to the Administrator who shall, within sixty days of receipt of the SAP report, determine whether to certify formal acceptance of the application for registration or deny the application and shall state the reasons therefor. If the Administrator finds that the SAP did not have substantial information before it to support a finding made by the majority, he shall, within 60 days of receipt of the SAP finding, determine whether to certify formal acceptance of the application or deny the application and shall state the reasons therefor.

Date	Proceedings
	III. The Administrator shall notify the applicant and Monsanto within three business days by certified mail of all certifications and denials under Part II of this Order. Any such certifications shall be final Agency actions not committed to Agency discretion by law and therefore judicially reviewable in the district courts pursuant to 16(a) of FIFRA. Any such denials shall be pursuant to 3(c)(6) of FIFRA and the applicant shall have the remedies set forth in FIFRA relating to Agency refusals to register pesticide products pursuant to 3(c)(6).  IV. During any period of time when there is not a validly constituted Scientific Advisory Panel established under 25(d)
	of FIFRA, the Administrator shall convene an advisory panel of no fewer than three members drawn from the members of the Scientific Advisory Board established under the Environmental Research, Development, and Demonstra-
	tion Authorization Act of 1978. Under those circumstances, the advisory panel shall perform the functions assigned to the Scientific Advisory Panel in Part I and II of this Order. All responsibilities of the Administrator under this Judgment may be performed by a properly designated delegate. V. Judgment requiring the terms and conditions is hereby entered. (cc: parties).
Aug. 31	Motion For Order Relating To Disclosures of Agency Documents Containing Monsanto Data submittals w/Memo In Support Thereof, by parties fld. (REF: 8-31-82).
Aug. 31	Joint Motion For Judgment Establishing Precedures To Evaluate Registration Applications In Light Of Disclosures of Monsanto Date, w/Memo in support thereof, by parties fld. (REF: 8-31-82).
Sept. 13	Post-Trial Brief, Proposed Findings of Fact and Proposed conclusion of Law, by Deft. fld.
Sept. 20	Reply Brief, by Pltff. fld. 9/23/82—Briefs having been filed, cause submitted to Judge Wangelin.
Oct. 27	Replacement of Page 2 of the Judgment entered by the Court on August 31, 1982, by parties fld. Substitution Ordered (HKW).
Nov. 22	
Nov. 29	

Date	Proceedings
Dec. 3	Letter To Judge Wangelin fld. by Pltf. 1/11/83—Briefs re-submit- ted to Judge Wangelin.
1983	
Jan. 28	Letter Directed To Judge Wangelin from Kenneth Heineman requesting that the attention of the Judge is brought to two recent decisions of the Supreme Court of the U.S. which directly support the positions advanced and authorities relied upon by Monsanto herein, fld.
Feb. 1	Letter To Judge Wangelin from Kenneth Heineman calling atten- tion to two recent decisions of the Supreme Court of the U.S.— U.S. v. Security Industrial Bank and Northern Pipeline Construc- tion Co. v. Marathon Pipeline Co., fld.
Feb 22	
Mar. 9	Memorandum In Response To Issues Raised In Conference with Court (in letterform addressed to Judge Wangelin), by Pltff. fld.
Mar. 10	Supplemental Post-Trail Brief, by Deft. fld.
Apr. 12	that §§ 3(cx(1xD), 3(cx(2xA), 10(b) and 10(d) of the Federal Insecticide, Fungicide and Rodenticide Act, as amended by Federal Pesticide Act of 1978, 7 U.S.C. § 136 et seq., are unconstitutional and unlawful and that they are beyond any power conferred by Congress by Article I, § 8, Clause 3 of the Constitution of the U.S. and are in violation of the Fifth Amendment thereto; It Is Further Ordered, Adjudged and Decreed that Deft., his officers, agents, employees and representatives be and they are hereby Permanently Enjoined from the implementation and enforcement, in any manner, directly or indirectly, of §§ 3(cx(1xD), 3(cx(2xA), 10(b) and 10(d) of the Federal Insecticide, Fungicide and Rodenticide Act, as amended by the Federal Pesticide Act of 1978; and
	It Is Further Ordered, Adjudged and Decreed that § 3(c(1)(D) of the Federal Insecticide, Fungicide and Rodenticide Act, as amended by the Federal Pesticide Act of 1978, does not authorize the deft. to use or consider in support of another's application for registration any of Pltff's information, research and test data submitted prior to January 1, 1970, and such use and consideration thereof by Deft. without Pltff's express written permission is unlawful; and It Is Further Ordered, Adjudged and Decreed that deft., his officers, agents, employees and representatives be and they are hereby Permanently Enjoined from any use or consideration for or disclosure to any other person of any of Pltff's information, research and test data, whenever submitted to deft. or his predecessors unless deft. shall have first obtained pltff's express written permission.

Date	Proceedings
	It Is Further Ordered that a Memorandum Opinion detailing the findings of fact and conclusions of law in support of this Judgment shall issue within six (6) days of this Judgment. (cc: parties).
Apr. 19	Memorandum (HKW), fld. (Pursuant to the Judgment entered on 4/12/83) (cc: parties).
Apr. 22	Motion For Amendment of Judgment For Clarification w/Suggestions In Support and Affidavit of W. Wayne Withers, by Pltff. fld. (REF: 5-9-83).
Apr. 22	Motion To Alter or Amend Judgment and Memorandum In Support Thereof, by Deft. fld. (REF: 5-9-83).
Apr. 22	Motion For Stay Pending Appeal, by Deft. fld. (REF: 5-9-83).
May 2	Response In Opposition To Deft's Motion For Stay Pending Appeal, by Pltff. fld.
May 2	Response In Opposition To Deft's Motion To Alter or Amend Judgment, by Pltff. fld.
May 2	Judgment For Clarification, by Deft. fld.
May 2	Motion For Leave To File Brief Amicus Curiae To Oppose Deft's Motion For Stay Pending Appeal, by attys for Amici Curiae fld. (REF: 5-2-83).
_ 1	5/5/83—Motion For Amendment of Judgment For Clarifica- tion fld. by Pltf. on 4/22/83 and Memo In Opposition fld. by Deft. on 5/2/83 submitted to Judge Wangelin.
	5/5/83—Motion To Alter or Amend Judgment and Motion For Stay Pending Appeal fid. by Deft. on 4/22/83 and Responses In Opposition to those motions fid. by Pltff. on 5/2/83 submitted to Judge Wangelin.
May 6	Motion For Order Shortening Time For Briefing and Hearing of Applicants' Application for leave to intervene under Rule 24, w/Memo of Points and Authorities In Support Thereof, by AFL-CIO and Natural Resources Defense Council, Inc. fld. (REF: 6-2-83).
May 6	Declaration of Michael Rubin In Support of Applicants' Motion For Order Shortening Time, fld.
May 6	
May 6	Declaration of Albert H. Meyerhoff, fld. 5/9/83—Morris Levin appeared before the Court relative to a Motion to Intervene.
- 1 - 1 - 1 - 1 - 1 - 1 - 1 - 1 - 1 - 1	Extension of Time Granted until 6/6/83 per Oral Order of (HKW) to appeal for AFL-CIO. Court delayed ruling of Motion to Intervene. Hearing on said motion may be held.
May 9	Nunc Pro Tunc Order (HKW)—It Is Hereby Ordered that page 39, lines 12 through 13 of the Court's Memorandum Opinion filed April 10, 1983 shall read as follows: contrary, the trial record amply demonstrates that competition in the pesticide industry is healthy and vibrant. (cc: parties).

Date	Proceedings
May 9	Order (HKW)—It is Hereby Ordered that except as set out in the Court's Amended Judgment of May 9, 1983, all post-trial motions filed by Monsanto Company and the EPA be and are Denied. (cc: parties).
May 9	
	It Is Further Ordered, Adjudged and Decreed that Deft., his officers, agents employees and representatives be and they are Permanently Enjoined from the implementation and enforcement, in any manner, directly or indirectly, of Sec. 3(cx(1)(D), the last sentence of Sec. 3(cx(2)(A), Sec. 10(b) of FIFRA, as amended by the Federal Pesticide Act of 1978; and
5	It is Further Ordered, Adjudged and Decreed that Sec. 3(cx1xD) of FIFRA, as amended by the Federal Pesticide Act of 1978, does not authorize the Deft. to use or consider in support of another's application for registration any of Pltff's information, research and test data submitted prior to January 1, 1970, and such use and consideration thereof by Deft. without Pltff's express written permission is unlawful; and
.00	It is Further Ordered, Adjudged and Decreed that Deft., his officers, agents, employees and representatives be and they are hereby Permanently Enjoined from any use or consideration for or disclosure to any other person, other than to representatives of other agencies of offices of the U.S. Government including the Committees or Houses of the U.S. Congress, of Pltf's information, research and test data, whenever submitted to Deft. or his predecessors, unless Deft. shall have first obtained Pltf's express written permission; and
	It is Further Ordered, Adjudged and Decreed that none of the aforesaid prevents the Deft. from approving applications for pesticide registrations as permitted under §§ 3(c)(5) and 3(c)(7) of FIFRA in cases where the applicant has submitted to EPA, and relied solely upon, his own data to support his application for registration; provided that any applicant for registration must either submit its own data, or cite its own previously submitted data, or cite data that appears in the public literature or cite the previously submitted date of another person with the prior written permission of such other person, and further that EPA is precluded from considering or using any other data in support of any application for registration. (cc: parties)
May 10 May 2	Notice of Appeal to the United States Supreme Court, by EPA fld.
May 2	Statement of Non-Resident Atty, fld.

Date	Proceedings
	5/10/83—Motion For Order Shortening Time for Briefing & Hearings, etc. fld. by AFL-CIO and Natural Resources Defense Council on 5/6/83 submitted to Judge Wangelin. 5/10/83—Application To Intervene fld. by AFl-CIO & Natural Resource Defense Council on 5/6/83 submitted to Judge Wangelin.
May 13	Transcript of Proceedings, fld.
May 13	Memorandum In Opposition To The Application of the AFL-CIO and NRDC To Intervene, by Pltff. fld
June 2	Order (HKW)—It Is Hereby Ordered that the AFL-CIO and NRDC's motion to intervene be and is Denied. (cc: parties)

# In the United States District Court for the Eastern District of Missouri

Monsanto Company, 800 North Lindbergh Boulevard,

St. Louis, Missouri 63166

### PLAINTIFF

U.

Douglas M. Costle, Administrator, Environmental Protection Agency,

401 M STREET, S.W., WASHINGTON, D.C. 20460,

#### DEFENDANT

Civil Action No. 79-0366-C(2)

FIRST AMENDED COMPLAINT FOR DECLARATORY JUDGMENT, INJUNCTIVE AND OTHER EQUITABLE RELIEF

Plaintiff, by and through its attorneys, for its First Amended Complaint for Declaratory Judgment, Injunctive and Other Equitable Relief, against defendant states as follows:

### JURISDICTION

1. This action arises under the Constitution of the United States, including Art. I, § 8, cl. 3 thereof and the Fifth Amendment thereto, under the Administrative Procedure Act, 5 U.S.C. § 551 et seq., and under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1331(a). The matter in controversy exceeds the sum of \$10,000, exclusive of interest and costs.

### THE PARTIES

2. Plaintiff, Monsanto Company, is incorporate in the State of Delaware and has its principal place of business in St. Louis County, Missouri. It is licensed to do business in the State of Missouri and resides in this judicial district. It owns and operates, in St. Louis County, Missouri,

its principal corporate and administrative offices and its major research facilities, including its pesticide products research facilities.

3. Defendant, Douglas M. Costle, is the Administrator of the United States Environmental Protection Agency (hereinafter "EPA"), and is charged with the implementation, administration and enforcement of the Federal Insecticide, Fungicide and Rodenticide Act, 7 U.S.C. §§ 135–136 et seq. (hereinafter "FIFRA"). Defendant is sometimes hereinafter referred to as the "Administrator".

## NATURE OF ACTION

- 4. Count I of this action is brought to restrain and redress the deprivation of plaintiff's civil and property rights secured to it by the Constitution and the Laws of the United States. Specifically, this action is brought to declare the illegality and unconstitutionality of the defendant's consideration and use for and disclosure to any third party of plaintiff's property consisting of its trade secret and confidential information, research and test data which it has submitted and will submit to defendant (and predecessor governmental agencies); to declare the illegality and unconstitutionality of Sections 3(c)(1)(D), 3(c)(2)(A), 10(b) and 10(d) of FIFRA, as amended by the Federal Pesticide Act of 1978, Pub. L. No. 95-396 (September 30, 1978); to revent, enjoin and restrain the unlawful deprivation and taking by said amended provisions of plaintiff's liberties, rights and property secured to it by the Constitution of the United States; and to prevent, enjoin and restrain defendant's unlawful consideration and use for, and disclosure to any third party of plaintiff's property, consisting of its trade secret and confidential information, research and test data which it has submitted and will submit to defendant (and predecessor governmental agencies).
- 5. Count II of this action is brought to declare the illegality and unconstitutionality of certain arbitrary, capricious and unlawful actions of the defendant and to prevent, restrain and enjoin defendant from such actions.

### THE STATUTORY BACKGROUND

- 6. Since FIFRA was first enacted in 1947, it has required the registration of all pesticides shipped in interstate commerce. Until 1970, the Secretary of the United States Department of Agriculture (hereinafter "USDA") administered FIFRA. Also, until 1970, the Secretary of Health, Education and Welfare, by and through the Food and Drug Administration (hereinafter "FDA"), was authorized to establish tolerances for pesticide chemicals in or on raw agricultural commodities under Section 408 of the Food, Drug and Cosmetic Act, 21 U.S.C. § 346a. These administrative functions of the USDA and FDA were transferred to EPA in December, 1970, by Reorganization Plan No. 3 of 1970, 35 Fed. Reg. 15623 (1970).
- 7. In order to obtain the registration of a pesticide under FIFRA, an applicant was required to support its application for registration with extensive information, research and test data demonstrating that the pesticide was effective for its recommended uses, and that it would perform its intended functions without unreasonable adverse effects on man, vertebrate animals and desirable vegetation. If use of the pesticide for which registration was sought could result in residues in or on raw agricultural commodities, the applicant was also required to submit in support of its application for registration extensive information, research and test data relating to the proposed application of the pesticide, its toxicity, the manner in which it was metabolized, its degradation, and its residues. This data was also required to be submitted in a petition for a tolerance for the pesticide for which registration was sought.
- 8. In October, 1972, FIFRA was amended by the Federal Environmental Pesticide Control Act of 1972, 86 Stat. 973. Pursuant to this amendment, the registration requirements were extended to pesticides shipped in intrastate commerce and authority was provided for the classification of pesticides and the regulation of their use. The requirements for information, research and test data to

- be submitted by an applicant for registration were retained, and, in addition, further requirements were imposed calling for the submission of information, research and test data to assess any risk to the environment which might result from any pesticide for which registration was sought.
- 9. The 1972 amendment of FIFRA authorized the Administrator in Section 3(c)(1)(D) of FIFRA to use and consider information, research and test data submitted by a previous applicant for registration to support the applications of subsequent applicants, but only upon satisfaction of either of two preconditions. An owner's data could be considered by the Administrator for the benefit of another only if the owner first granted his permission or if the person for whose benefit the data would be used agreed to pay reasonable compensation to the owner. If the parties could not agree as to compensation, the Administrator was authorized to determine such compensation, subject to judicial review. If, however, any of the data to be considered contained or related to trade secrets or other information protected from disclosure by Section 10(b), then without the owner's permission it could not be used at all.
- 10. Section 10(b) of FIFRA, as amended in 1972, prohibited the disclosure of any information, research and test data of an applicant which contains or relates to trade secrets or other confidential or privileged commercial or financial information.

## PLAINTIFF'S DATA

- 11. Plaintiff has engaged in research and development activities with respect to agricultural and other pesticides for many years. It has played a leading role in the development of agricultural herbicides which are safe and effective.
- 12. for many years prior to December, 1970, pursuant to the requirements of FIFRA, plaintiff submitted substantial information, research and test data to the USDA and the FDA in support of many applications for registra-

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tion of pesticides under FIFRA and petitions for tolerances. Since December, 1970, through the present, it has submitted and will in the future submit substantial information, research and test data to the EPA for these purposes, which submissions have been and will be made pursuant to the requirements of FIFRA.

13. On the basis of the information, research and test data submitted by it, plaintiff has obtained registrations under FIFRA for many pesticide products, most of which are currently produced and sold by it and for which it has developed substantial domestic and foreign markets. Plaintiff has submitted under FIFRA to defendant or defendant's predecessor agencies information, research and test data with respect to the following products:

Product name	Active pesticide ingredient	Active ingredient common name.
Avadex*	S-(2, 3-Dichloroallyl)-diisopropylthiocarbamate.	Diallate.
Avadex* Granular.	S-(2, 3-Dichloroallyl)-diisopropylthiocarbamate.	Diallate.
Avadex* BW	S-(2,3,3-Trichloroallyl)- diisopropylthiocarbamate.	Triallate.
Far-Go*	S-(2,3,3-Trichloroallyl)- diisopropylthiocarbamate.	Triallate.
Machete*	2-chloro-2', 6'-diethyl-N-(butox- ymethyl) acetanilide.	Butachlor.
Far-Go* Granular.	S-(2,3,3-Trichloroallyl)- diisopropylthiocarbamate.	Triallate.
Lasso*	2-chloro-2', 6'-diethyl-N-(methoxymethyl) acetanilide.	Alachlor.
Lasso* II	2-chloro-2', 6'-diethyl-N-(methoxymethyl) acetanilide.	Alachlor.
Niran* 6-3		Parathion," Methyl Parathion.
Parathion Technical.	0, 0-diethyl 0-p-nitrophenyl phosphorothioate.	Parathion.

Product name	Active pesticide ingredient	Active ingredient common name.
Methyl Parathion. Polaris*	0, 0-dimethyl 0-p-nitrophenyl phosphorothioate. N, N-bis-(phosphonomethyl)-	Methyl Parathion. Glyphosine.
	glycine.	Cityphospic.
Ramrod*/ Atrazine.	2-chlorop-N-isopropylace- tanilide; 2-chloro-4-(ethyla- mino)-6-(isopropyl-amino)-s- triazine.	Propachlor/ Atrazine.
Ramrod* 20 Granu- lar.	2-chloro-N-isopropylace- tanilide.	Propachlor.
Ramrod* 65	2-chloro-N-isopropylace- tanilide.	Propachlor.
Randox*	2-chloro-N, N-diallylacetamide	Allidochlor.
Randox* Granular.	2-chloro-N, N-diallylacetamied	
Roundup*	Isopropylamine salt of N- (phosphonomethyl) glycine.	Isopropylamine Salt of Glyphosate.
Vegadex*	2-chloroallyl diethyl-dithiocar- bamate.	Sulfallate.
Vegadex* Granular.	2-chloroallyl diethyldithio-car- bamate.	Sulfallate.
Rogue*	3', 4'-dichloropropionanilide	Propanil.
Plus-de-Ris*	3', 4'-dichloropropionanilide	Propanil.
Santophen* 1 Germicide.	Ortho-benzyl- parachlorophenol.	Chlorophene.
Santophen* 1 Solution.	Ortho-benzyl- parachlorophenol.	Chlorophene.
None	3, 4, 4' trichlorocarbanilide	Trichlocarban.
ACL* 56 Sanitizer and	Sodium dichloro-s-triazine trione dihydrate.	Sodium dichloroiso- cyanurate
Bleaching Compound.		dihydrate.

Product name	Active pesticide ingredient	Active ingredient common name.
ALC* 59 Santizer and Bleaching Compound.	Potassium dichloro-s-triazine trione dihydrate.	Potassium dichloroiso- cyanurate dihydrate.
ACL* 60 Sanitizer and Bleaching Compound.	Sodium dichloro-s-triazine trione.	Sodium dichloroiso- cyanurate.
ACL* 66 Sanitizer and Bleaching Compound.	(Monotrichloro) tetra- (Mono- potassium dichloro)-penta-s- triazine trione.	(Monotrichloro) tetra- (Monopotas- sium dichloro)- pentaisocyan- urate.
ALC* 85 Sanitizer and Bleaching Compound.	Trichloro-s-triazine trione	Trichloroiso- cyanuric acid.

<sup>\*</sup>Registered Trademark of Monsanto Company.

- 14. Plaintiff has spent and currently spends multi-millions of dollars annually in research and development activities to develop, maintain and expand its registered pesticide products. To conduct these research and development activities, plaintiff presently employs more than 450 personnel, the majority of whom have advance degrees in chemistry, one of the biological sciences, agronomy or plant physiology.
- 15. The direct historical cost incurred by plaintiff to develop the information, research and test data submitted by it under FIFRA to secure and maintain the registration of its products is in excess of 100 million dollars. The development by others of the information, research and

test data submitted by plaintiff would be extremely difficult, if at all possible, and would require the highest exercise of sophisticated scientific expertise and ingenuity for thousands of man-years together with the expenditure of enormous sums of money. Most of this information, research and test data is and has been confidentially maintained by plaintiff and stringent security measures are taken to preserve its secrecy. Most of this information, research and test data has not been disclosed by plaintiff except in condfidence to EPA and other governmental agencies pursuant to their regulatory requirements, and heretofore its confidentiality has been preserved by these agencies.

- 16. This information, research and test data is used by plaintiff in the development of additional formulations for its registered products and in the development of new products which are chemically related to products previously developed by it. It has substantial and incalculable continuing value to plaintiff and affords it a significant competitive advantage in the conduct of its business.
- 17. By developing this information, research and test data, plaintiff, as owner thereof, has acquired and will continue to acquire trade secrets and confidential commercial interests therein. [Not in development, but in maintenance.]
- 18. The use and consideration for or disclosure to any third party by defendant of this trade secret and confidential information, research and test data will irreparably injure plaintiff in the conduct of its business, and will confer an immediate and substantial competitive advantage upon its competitors by advancing significantly the state of their technology and by permitting the registration of their products, both in the United States and in foreign countries, without incurring the enormous costs of research and development.

#### COUNT I

Plaintiff incorporates herein and realleges paragraphs 1 through 18 of this First Amended Complaint.

20. Section 2 of the Federal Pesticide Act of 1978 (hereinafter "FPA") amends Sections 3(c)(1)(D) and 3(c)(2) of FIFRA, and Section 15 of the FPA amends Section 10 of FIFRA.

## USE AND CONSIDERATION OF PLAINTIFF'S DATA

- 21. Section 3(c)(1)(D) of FIFRA, as amended by the FPA, makes plaintiff's property, that is, all of the valuable information, research and test data which plaintiff has submitted and will in the future submit, including its trade secrets and other confidential commercial information, available for use by plaintiff's competitors in obtaining pesticide registrations, without plaintiff's permission. This Section, as amended, takes plaintiff's property for private purposes and without just compensation.
- 22. The allegations set forth in paragraph 21 are predicated upon the Administrator's intepretation of FIFRA as authorizing him to use and consider information, research and test data submitted by plaintiff prior to January 1, 1970, in support of the applications of plaintiff's competitors without compensation to plaintiff for such use. Information, research and test data submitted by plaintiff subsequent to December 31, 1969, may, with certain exceptions, be used and considered by the Administrator for this purpose upon an applicant's mere "offer to compensate", with said applicant's registration to be granted even though compensation for such use may not have been paid or even determined.
- 23. Section 3(c)(1)(D) also provides binding arbitration procedures respecting this taking and deprivation of plaintiff's property which are devoid of any standards for determining the amount of compensation and expressly deny plaintiff recourse to the Courts. It compels plaintiff's submission to such procedures without plaintiff's prior agreement or consent. If plaintiff does not submit to or participate in these procedures, it forever forfeits any compensation whatsoever.

## DISCLOSURE OF PLAINTIFF'S DATA

24. Section 3(c)(2(A) of FIFRA, as amended by the FPA, requires the public disclosure of most of plaintiff's valuable information, research and test data it has submitted, including its trade secrets and other confidential commercial information, without plaintiff's permission and without affording plaintiff any notice of or opportunity to be heard in opposition to it.

25. Sections 10(b) and 10(d) of FIFRA, as amended by the FPA, permit the public disclosure of plaintiff's valuable information, research and test data it has submitted, including its trade secrets and other confidential commercial information, without plaintiff's permission and without affording plaintiff any notice of or opportunity to be

heard in opposition to it.

26. Sections 3(c)(2)(A), 10(b) and 10(d) of FIFRA, as amended by the FPA, compel the disclosure to the public and to plaintiff's competitors of plaintiff's trade secrets and confidential commercial information, thereby irrevocably destroying their value and plaintiff's property in them.

#### ILLEGALITY OF CHALLENGED PROVISIONS

27. Sections 3(c)(1)(D), 3(c)(2)(A), 10(b) and 10(d) of FIFRA, as amended by the FPA, wholly deprive plaintiff of its property rights in and to the trade secret and confidential information, research and test data it has submitted under FIFRA. These Sections, as amended, are unconstitutional in that they are beyond any power conferred on the Congress by Article I, § 8, cl. 3 of the Constitution and are violative of the Fifth Amendment in that they deprive plaintiff of its property and liberty of contract without due process of law, take its property without just compensation and for a private purpose, deny to plaintiff equal protection of the laws, and deprive plaintiff of its right to a judicial determination of the value of property taken from it. Unless Sections 3(c)(1)(D), 3(c)(2)(A), 10(b) and 10(d) of FIFRA, as amended by the FPA, are declared unlawful and their operation and execution preliminary and permanently enjoined, plaintiff's business will be irreparably injured, its Consitutional rights and liberties irrevocably impaired, and its property destroyed. Plaintiff has no other adequate remedy to prevent the unconstitutional excesses and deprivations effected by these amendments.

## RELIEF REQUESTED

WHEREFORE, plaintiff prays for and requests the following relief:

- 1. That the Court enter its Declaratory Judgment declaring that Sections 3(c)(1)(D), 3(c)(2)(A), 10(b) 10(d) of FIFRA, as amended by the FPA, are unconstitutional and unlawful in that they are beyond any power conferred on the Congress by Art. I, § 8, cl. 3 of the Constitution of the United States and are in violation of the Fifth Amendment thereto;
- 2. That the Court grant plaintiff equitable relief and enter its judgment restraining and enjoining, preliminarily and permanently, the defendant, his officers, agents, employees and representatives from the implementation and enforcement, in any manner, directly or indirectly, of Sections 3(c)(1)(D), 3(c)(2)(A), 10(b) and 10(d) of FIFRA, as amended by the FPA:
- 3. That the Court grant plaintiff equitable relief and enter its judgment restraining and enjoining, preliminarily and permanently, the defendant, his officers, agents, employees and representatives from any use or consideration for or disclosure to any other person of any of plaintiff's trade secret and confidential information, research and test data, whenever submitted, unless defendant shall have first obtained plaintiff's express written permission; and
- That the Court grant plaintiff such other and further lawful and equitable relief as may be just and proper.

### COUNT II

In the alternative to that part of the relief requested in Count I pertaining to the Administrator's use and consideration of plaintiff's information, research and test data submitted prior to January 1, 1970, and without prejudice to plaintiff's entitlement to the relief otherwise requested by plaintiff in Count I, plaintiff for its Count II, states as follows:

- 1. Plaintiff incorporates herein and realleges paragraphs 1 through 18 of this First Amended Complaint and paragraph 20 of Count I of this First Amended Complaint.
- 2. If Section 3(c)(1)(D) of FIFRA, as amended by the FPA, does not authorize or require the defendant to use or consider in support of another person's application for registration any of the information, research and test data submitted by plaintiff prior to January 1, 1970, such use and consideration by defendant is illegal and unconstitutional. Unless the relief sought herein is granted, defendant will use and consider in support of the applications for registration of plaintiff's competitors, the information, research and test data submitted by plaintiff prior to January 1, 1970, without plaintiff's permission and without any compensation to plaintiff whatsoever.
- 3. The defendant's use and consideration in support of another person's application for registration of plaintiff's information, research and test data submitted prior to January 1, 1970, is illegal in that such use and consideration (a) arbitrarily, capriciously and unlawfully deprives plaintiff of its rights to prevent the unauthorized use by others of its proprietary information, research and test data, including its trade secrets and confidential commercial information, and (b) unconstitutionally deprives plaintiff of its property without due process of law and constitutes a taking for private purposes and without just compensation, all in violation of the Fifth Amendment.
- 4. Unless defendant's use and consideration in support of another person's application for registration of plain-

tiff's information, research and test data submitted prior to January 1, 1970, is declared unlawful and he is enjoined therefrom, plaintiff's proprietary interests therein will be irrevocably impaired and its business irreparably injured. Plaintiff has no adequate remedy at law or through any administrative procedure to prevent the unlawful and unconstitutional deprivation by defendant of plaintiff's rights in its information, research and test data submitted prior to January 1, 1970.

## RELIEF REQUESTED

WHEREFORE, plaintiff prays for and requests, in the alternative, the following relief with respect to its information, research and test data submitted prior to January 1, 1970, and without prejudice to plaintiff's entitlement to the relief otherwise requested by plaintiff in Count I:

- 1. That the Court enter its Declaratory Judgment declaring that Section 3(c)(1)(D) of FIFRA, as amended by the FPA, does not authorize or require the defendant to use or consider in support of another's application for registration plaintiff's information, research and test data submitted prior to January 1, 1970:
- 2. That the Court enter its Declaratory Judgment declaring that the defendant's use and consideration in support of another's application for registration of plaintiff's information, research and test data submitted prior to January 1, 1970, is unlawful;
- 3. That the Court grant plaintiff equitable relief and enter its judgment restraining and enjoining, preliminarily and permanently, the defendant, his officers, agents, employees and representatives from any use or consideration in support of another's application for registration of plaintiff's information, research and test data submitted prior to January 1, 1970, unless defendant shall have first obtained plaintiff's express written permission, and

4. That the Court grant plaintiff such other and further lawful and equitable relief as may be just and proper.

LATHROP, KOONTZ, RIGHTER, CLAGETT, PARKER & NORQUIST,

JOSEPH E. STEVENS, Jr., GARY S. DYER, C. DAVID BARRIER.

2600 Mutual Benefit Life Bldg.,

2345 Grand Avenue, Kansas City, Missouri 64108, (816) 849-00

(816) 842-0820.

COBURN, CROFT, SHEPHERB, MERZOG & PUTZELL,
THOMAS L. CROFT,
One Mercantile Center,
St. Louis, Missouri 63101,
(314) 621-8575.

Attorneys for Plaintiff, Monsanto Company.

### CERTIFICATE OF SERVICE

This is to certify that the foregoing was served by placing copies thereof in the United States Mail, postage prepaid, this 30th day of May, 1979, addressed to: Stephen D. Ramsey, United States Department of Justice, Room 1732, Washington, D.C. 20530 and Ann Travis, Assistant United States Attorney, U.S. Court & Customs House, 1114 Market St., St. Louis, Missouri 63101, attorneys for defendant, Douglas M. Costle.

Thomas L. Croft.

# In the United States District Court for the Eastern District of Missouri

(Civil Action No. 79-0366-C(2))

Monsanto Company, 800 North Lindburgh Boulevard, St. Louis, Missouri 63166, plaintiff

U.

Douglas M. Costle, Administrator, Environmental Protection Agency, 401 M Street, S.W., Washington, D.C. 20460, defendant

# Defendant's Answer

Now comes Douglas M. Costle, Administrator of the United States Environmental Protection Agency, and makes his answer to plaintiff's first amended complaint as follows:

#### FIRST DEFENSE

Plaintiff has failed to state a claim upon which relief can be granted.

### SECOND DEFENSE

Count II of plaintiff's complaint is not ripe and there is no case or controversy underlying this claim.

#### THIRD DEFENSE

Defendant answers seriatim the numbered paragraphs of plaintiff's complaint.

- 1.) Defendant admits the Court has jurisdiction of plaintiff's claim.
  - 2.) Admitted.
  - 3.) Admitted.
- 4.) Paragraph 4 of plaintiff's complaint contains a summary of its allegations and states the "Nature of [plaintiff's] Action." To the extent this paragraph contains any factual allegations, it is denied.
- 5.) Paragraph 5 of plaintiff's complaint contains a summary of its allegations and states the "Nature of [plain-

tiff's] Action." To the extent this paragraph contains any factual allegations, it is denied.

- 6.) Admitted.
- 7.) Admitted that initial registrations for specified uses of products containing particular active ingredients under FIFRA as enacted in 1947 required the type of data support outlined in paragraph 7 of plaintiff's complaint. However, subsequent registrations of products with the same active ingredient and the same use as a product already registered were not required to be supported by the type of data submission alleged by plaintiff. Instead, the Agency's predecessors regularly considered data submitted by one registrant in support of another, subsequent application for registration from any person for a product containing the same active ingredient and used for the same purpose as that already registered.
- 8.) FIFRA was also amended in 1975 by Pub. L. 94-140; and 1978 by Pub. L. 95-396. These different versions of FIFRA will be referred to as '72 FIFRA, '75 FIFRA and '78 FIFRA. Defendant admits the first two sentences of paragraph 8 of plaintiff's complaint. Defendant denies the remainer of paragraph 8.
- 9.) Admitted as to the 1972 and the 1975 versions of FIFRA.
- 10.) Admitted as to the 1972 and the 1975 versions of FIFRA.
- 11.) Defendant admits the allegations contained in the first sentence of paragraph 11 of plaintiff's complaint. Defendant admits that plaintiff has obtained registrations for agricultural herbicides. Defendant lacks knowledge sufficient to admit or deny the remaining allegations of paragraph 11 of plaintiff's complaint.
- 12.) Defendant admits the allegations contained in paragraph 13 of plaintiff's complaint, except as to the future actions of plaintiff, which are unknown to defendant and which defendant lacks knowledge sufficient to admit or deny.

- 13.) Defendant admits that plaintiff has submitted to defendant, U.S.D.A. and the F.D.A. information, research and test data with respect to the products listed in paragraph 13 of plaintiff's complaint. Defendant further admits that plaintiff has obtained registrations for many pesticide products and sells them both in the United States and in foreign countries.
- 14.) Defendant admits that plaintiff has spent and currently spends substantial amounts of money in the research and development of pesticide products and employs persons to engage in such activities. Defendant is without knowledge sufficient to admit or deny the exact amount of money spent on or persons employed by plaintiff to engage in research and development of its pesticide products.
- 15.) Defendant lacks knowledge sufficient to admit or deny the allegations contained in the first, third and fourth sentences of paragraph 15 of plaintiff's complaint. Defendant denies the allegations contained in the second sentence of this paragraph.
- 16.) Defendant lacks knowledge sufficient to admit or deny the allegations contained in paragraph 16 of plaintiff's complaint.
  - 17.) Denied.
  - 18.) Denied.

### COUNT I

- 19.) Defendant incorporates and here realleges his responses to paragraphs 1-17 of plaintiff's complaint.
  - 20.) Admitted.
- 21.) Defendant disagrees with and denies the inaccurate and incomplete legal conclusion contained in paragraph 21 of plaintiff's complaint.
- 22.) Defendant is not required either to admit or deny the statement contained in the first sentence of paragraph 22 of plaintiff's complaint. The legal conclusions contained in the second sentence of this paragraph is incomplete and misleading. Section 3(C(1)(D)(i) and (ii) of FIFRA, as amended by the Federal Pesticide Act of 1978,

authorizes the Administrator of EPA to consider data submitted by one data submitted in support of a third party's subsequent application for registration of a pesticide product under certain circumstances.

- a.) Data submitted prior to December 31, 1969. It is defendant's position that he may consider such data in support of third party applications for registration without the permission of the original data submitter and without requiring an offer of compensation to be made to the original submitter. See Section 3(C)(1)(D)(iii).
- b.) Data submitted after December 31, 1969, in support of a registration granted on or before September 30, 1978. It is the Administrator's position that he may consider data submitted during this time in support of third party applications with the permission of the original submitter only if an offer of compensation has been made to the original data submitter. The original submitter's right to compensation is limited to a fifteen year period after the expiration of which the Administrator may use the data without permission of the original submitter and without requiring an offer of compensation to the original submitter. See Section 3(C)(1)(D)(ii).
- c.) Data submitted in support of registrations granted after September 30, 1978. Section 3(C)(1)(D)(i) provides that the Administrator may not, without the written permission of the original data submitter, consider such data to support an application of another person during a period of ten years following the date the Administrator first registers a pesticide. The "exclusive use" provisions of sec. 3(C)(1)(D)(i) do not apply to "defensive data." After such ten year period the Administrator may use the data without the permission of the original data submitter subject to the compensation provisions of Sec. 3(C)(1)(D)(ii). See paragraph b above. Concurrently with this ten year period, Sec. 3(C)(1)(D)(ii) provides that for fifteen

years after the date the data was originally submitted the Administrator may consider such data in support of an application by any other person only if such person has made an offer to compensate the original data submitter. Thus, the Administrator may consider "non-defensive" data to support a third party application for registration during the ten year period following its submission only if a.) he has the permission of the original submitter to do so in accordance with Sec. 3(C)(1)(D)(i) and b.) the original submitter has received an offer of compensation from the applicant desiring to rely on data in accordance with Sec. 3(C)(1)(D)(ii). For the next five year period, an offer to compensate the original submitter is the only restriction on the Administrator's use of the data to support another person's application for registration. Thereafter, the Administrator may consider such data in support of third party applications for registration without permission and without requiring an offer to compensate the original submitter.

23.) Defendant admits that Sec. 3(C)(1)(D) provides for binding arbitration in the event the parties cannot agree on terms for compensation for the use of an original submitter's data. Defendant further admits that the failure by an original data submitter to participate in a procedure for reaching an agreement or in an arbitration agreement or failure to comply with the terms of an agreement or arbitration decision concerning compensation under Sec. 3(C)(1)(D)(ii) will result in the forfeiture of the original submitter's right to compensation for the use of the data in support of the application. Defendant admits that, except upon a showing of fraud, misrepresentation or other misconduct by one of the parties to the arbitration or the arbitrator, the findings and determination of the arbitrator shall be final and not judicially or adminstratively reviewable. Defendant denies the remainder of the allegations contained in paragraph 23 of plaintiff's complaint.

#### COUNT II

24.) Defendant disagrees with and denies the incomplete and inaccurate legal conclusion contained in paragraph 24 of plaintiff's complaint.

25.) Defendant disagrees with and denies the incomplete and inaccurate legal conclusion contained in para-

graph 25 of plaintiff's complaint.

26.) Defendant disagrees with and denies the incomplete and inaccurate legal conclusion contained in paragraph 26 of plaintiff's complaint.

27.) Denied.

Wherefore, defendant requests the Court to deny plaintiff all the relief it has requested, to tax costs against plaintiff for general relief.

Respectfully submitted,

## ROBERT KINGSLAND,

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ANNE TRAVIS,

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Of counsel: Alice Wegman, Edward C. Gray; Pesticides Division, Office of General Counsel, Environmental Protection Agency, Washington, D.C. 20460.

### CERTIFICATE OF SERVICE

I hereby certify that on this 26th day of July, 1979, I mailed a copy of the foregoing Defendant's Answer to the following counsel of record:

Lathrop, Koontz, Righter, Clagett, Parker & Norquist; 2600 Mutual Benefit Life Building; 2345 Grand Avenue; Kansas City, Missouri 64108.

Kenneth R. Heineman, Esquire; Coburn, Croft, Sheperd, Herzog & Putzell; Suite 2900; One Merchantile Center; St. Louis, Missouri 63101.

STEPHEN D. RAMSEY.

# In the United States District Court for the Eastern District of Missouri, Eastern Division

# MONSANTO COMPANY, PLAINTIFF

U.

# Douglas M. Costle, Administrator, Environmental Protection Agency, defendant

Civil Action No. 79-0366-C(1)

## FIRST SUPPLEMENTAL STIPULATION OF FACTS

The following facts are hereby stipulated and agreed to by and between the parties herein by their undersigned counsel. These stipulations are for the purpose of this case only and do not constitute admissions of either party in any other case or in any other context:

- (1) That much of Monsanto's information, research and test data that it has submitted under FIFRA to EPA and its predecessor agencies contains or relates to trade secrets as defined by the Restatement of Torts and confidential, commercial information.
- (2) That Monsanto has certain property rights in its information, research and test data that it has submitted under FIFRA to EPA and its predecessor agencies which may be protected by the Fifth Amendment to the Constitution of the United States.

LATHROP, KOONTZ, RIGHTER, CLAGETT, PARKER & NORQUIST,

/S/ Joseph E. Stevens, Jr.,

/S/ C. David Barrier,

/S/ Gary S. Dyer,

2600 Mutual Benefit Life Building, 2345 Grand Avenue, Kansas City, Missouri 64108, (816) 842– 0820.

# COBURN, CROFT & PUTZELL,

/S/ Thomas L. Croft,

/S/ Kenneth R. Heineman,

One Mercantile Center, Suite 2900, St. Louis, Missouri 63101, (314) 621-8575, Counsel for Plaintiff.

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Of counsel: Alice Wegman, Edward C. Gray; Pesticides Division; Office of General Counsel; Environmental Protection Agency; Washington, D.C. 20460; Counsel for defendant.

# In the United States District Court for the Eastern District of Missouri, Eastern Division

MONSANTO COMPANY, PLAINTIFF,

U.

ANNE M. GORSUCH, ADMINISTRATOR, ENVIRONMENTAL PROTECTION AGENCY, DEFENDANT

Civil Action No. 79-0366-C(1)

# MONSANTO'S PROPOSED FINDINGS OF FACTS

1. Plaintiff, Monsanto Company, is incorporated in the State of Delaware and has its principal place of business in St. Louis County, Missouri. Plaintiff owns and operates its principal corporate and administrative offices, and its major research facilities in St. Louis County, Missouri. It is licensed to do business in the State of Missouri and resides in this judicial district.

(AGREED), 1

<sup>&</sup>lt;sup>1</sup> Following those Findings of Fact which plaintiff proposed in support of its Cross Motion for Summary Judgment and to which defendant has agreed, the notation "AGREED" will appear (see defendant's Response to Plaintiff's Proposed Findings of Material Facts). As to those Findings of Fact which plaintiff submitted in support of its Cross Motion for Summary Judgment which are marked "NOT CONTRO-VERTED", defendant failed to controvert the substantive content of said Findings of Fact, and did in fact state her basic agreement with them, but also except with regard to one such Finding (No. 77) stated that since plaintiff's information to which reference is made in said Findings of Fact is not submitted to defendant under FIFRA as amended in 1378 and thus further is not disclosable thereunder, such Findings of Fact are irrelevant (see Defendant's Response to Plaintiff's Proposed Findings of Material Facts). Plaintiff submits that such uncontroverted Findings of Fact are relevant, and should be entered by the Court herein because they demonstrate the enormous amount of time, money and highly sophisticated scientific effort which must be expended in connection with the development of the information, research and test data which is submitted to defendant pursuant to FIFRA in order to support and maintain the registration of plaintiff's pesticide products, which said information, research and test data will Continued

15. Plaintiff has engaged in research and development activities with respect to agricultural and other pesticides for many years. For many years prior to December, 1970, plaintiff submitted substantial information, research and test data to the USDA and the FDA in support of many applications for registration of pesticides under FIFRA and petitions for tolerances. Since December, 1970, through the present, it has submitted substantial information, research and test data to the EPA for these purposes.

## (AGREED).

16. On the basis of the information, research and test data submitted by it, plaintiff has obtained registrations under FIFRA for many pesticide products, most of which are currently produced and sold by it and for which it has developed substantial domestic and foreign markets. Plaintiff has submitted under FIFRA to defendant or defendant's predecessor agencies information, research and test data with respect to the following products:

Product name	Active pesticide ingredient	Active ingredient common name
Avadex*	S-(2,3,-Dichloroallyl)- diisopropylthiocarbamate	Diallate.
Avadex* Granular	S-(2,3,-Dichloroallyl)- diisopropylthiocarbamate	Diallate.
Avadex* BW	S-(2,3,3-Trichloroallyl)- diisopropylthiocarbamate	Triallate.
Far-Go*	S-(2,3,3-Trichloroallyl)- diisopropylthiocarbamate	Triallate.
Far-Go* Granular	S-(2,3,3,-Trichloroallyl)- diisopropylthiocarbamate	Triallate.

be disclosed pursuant to the 1978 amendments to FIFRA which plaintiff has challenged herein, all of which is demonstrated by the record herein. As to all other Findings of Fact, a citation to particular portions of the transcript of the trial of this case held March 8-12, 1982, and/or citation to particular exhibits introduced therein, or citation to evidence of which the Court can take judicial notice will appear following the notation "Record Reference".

Product name	Active pesticide ingredient	Active ingredient common name
Lasso*	2-chloro-2',6'-diethyl-N (methoxymethyl) acetanilide	Alachlor.
Lasso* II		Alachlor.
Niran* 6-3		Parathion; Methyl Parathion.
Parathion Technical	0-0-diethyl 0-p-nitrophenyl phosphorothioate	Parathion.
Methyl Parathion	0,0-dimethyl 0-p-nitrophenyl phosphorothioate	Methyl Parathion.
Polaris*	N,N-bis-(phosphonomethyl)- glycine	Glyphosine.
Ramrod*/ Atrazine.	2-chloro-N-isopropylace tani- lide; 2-chloro-4-(ethylamino)- 6-(isopropyl-amino)-s- triazine	Propachlor/ Atrazine.
Ramrod* 20 Granular	2-achloro-N-isopropylace tani- lide; 2-chloro-4-(ethylamino)- 6-(isopropylace tanilide	Propachlor.
Ramrod* 65	2-chloro-N-isopropylace tani- lide	Propachlor.
Randox*	2-chloro-N,N-diallylacetamide	Allidochlor.
Randox* Granular	2-chloro-N,N-diallylacetamide	Allidochlor.
Roundup*	Isopropylamine salt of N- (phosphonomethyl) glycine	Isopropylamine Salt of Glyphosate.
Vegadex*	2-chloroallyl diethyl dithiocar- bamate	Sulfallate.
Vegadex* Granular	2-chloroallyl diethyldithio car- bamate	Sulfallate
Machete*	2-chloro-2', 6'-diethyl N(butoxymethyl) acetani- lide	Butachlor.
Rogue*	3',4'-dichloropropionanilide	Propanil.
Plus-de-Ris*	3',4'-dichloropropionanilide	Propanil.

Product name	Active pesticide ingredient	Active ingredient common name
Santophen* 1 Germicide.	Ortho-benzyl- parachlorophenol	Chlorophene.
Santophen* 1 Solution	Ortho-benzyl- parachlorophenol	Chlorophene.
None	3,4,4' trichlorocarbanilide	Trichlocarban.
ACL* 56 Sanitizer and Bleaching Compound	Sodium dichloro-s-triazine trione dihydrate	Sodium dichloroiso- cyanurat dihydrate.
ACL* 59 Sanitizer and Bleaching Compound	Potassium dichloro-s-triazine trione dihydrate	Potassium dichlordiso- cyanurate.
ACL* 60 Sanitizer and Bleaching Compound	Sodium dichloro-s-triazine trione	Sodium dichloroiso- cyanurate.
ACL* 66 Sanitizer and Bleaching Compound	(Monotrichloro) tetra (Mono- potassium dichloro)-penta-s- triazine trione	(Monotrichloro tetra- (Menopotas- siu dichloro)- penta
ACL* 85 Sanitizer and Bleaching	Trichloro-s-triazine trione	Trichloroiso- cyanuric acid.
Compound		
Polado*	Sesqui-sodium salt of N-(Phosphonomethyl) glycine	Glyphosate.

<sup>\*</sup>Registered Trademark of Monsanto company.

# (AGREED).

18. A company's decision to develop pesticides requires it to make major commitments long before it can antici-

pate developing a commercial pesticide and even longer before it can expect any return on its investment. First, the company must synthesize, test and evaluate candidate pesticides typically for 4 to 8 years before it will identify a commercial candidate. It must then conduct extensive research for at least 6 additional years, including 2 years to obtain registration, before it can anticipate first marketing a product. Generally, a further 4 to 8 years will elapse before that product reaches a point where its costs of discovery, development and commercialization have been recovered. Second, the company must commit to the employment of a large scientific research group representing many disciplines, and to the acquisition of the necessary physical facilities and sophisticated equipment to conduct the intensive research required to assure some reasonable probability of success in discovering and commercializing a candidate pesticide. Third, any such company must commit to the expenditure of \$5 million to \$15 million annually for several years before it will develop a potential commercial pesticide candidate. Even then, it will not know whether the candidate will become a commercial product until it has conducted further evaluation for an additional four or more years. This further evaluation could dictate that the candidate be rejected at any point during its development, even in the final year of its further evaluation.

# (NOT CONTROVERTED).

19. Once a target is selected, a company must devise extremely efficient, unique and technically sound ways of determining what compounds should be synthesized. The Company's chemists are not only concerned with synthesizing new chemicals, but equally important, are concerned with new chemical processes, techniques, and methods of synthesis to facilitate their invention of such new chemicals. Once a company decides that a new area of chemistry might be fruitful, these chemists then proceed to develop and synthesize new compounds in that area of chemistry. These new compounds are referred to

biologists who determine whether they are biologically active and whether they are pesticide candidates. This biological information is crucial in making the difficult technical judgment whether a compound is worthy of further study. The biologists and the chemists then examine and discuss the results to determine which directions, if any, offer further leads. Using the knowledge obtained from these discussions, the chemists synthesize more new compounds in the directions in which leads are expected. This constant dialogue takes place between literally dozens of organic chemists and biologists and is what ultimately produces the lead which results in a new commercial pesticide.

## (NOT CONTROVERTED).

20. Decisions on most of the thousands of chemicals synthesized by plaintiff are made after an initial evaluation called a primary screen which allows plaintiff to determine the probability of a compound becoming commercially successful. With most compounds, this probability is virtually zero, and these compounds are rejected.

# (NOT CONTROVERTED).

21. The remaining compounds reach the secondary screen, a much more intensive evaluation involving more complex methods of evaluating the compound's chemistry and biological activity. This stage includes studies in the greenhouse, controlled climate rooms, growth chambers, and limited small plot field tests.

# (NOT CONTROVERTED).

22. Only about one in one thousand compounds will survive these first two screenings. For those which survive, field tests are carried out in which the chemical is applied under conditions simulating those of actual agricultural use. If plaintiff decides to commercialize a compound, the commitment to do so must be made at this point. Then, a battery of separate but coordinated activities must also be commenced. It must be determined how the compound can be formulated in order that it can be easily, safely and effectively used by the farmer in the

field. The process chemists and engineers must begin planning to determine how the product can be safely and efficiently produced at the lowest cost in million-pound quantities as opposed to the few grams previously made in test tubes. Acute toxicology tests must be conducted to determine if and how the compounds can be safely used. Expanded field work, metabolism and long term toxicology testing must be initiated. All of these interrelated and interdependent activities must progress to completion at the same time in order that one of them does not become a limiting factor in the development program. Thereafter, full research and development programs proceed with the knowledge that unknown factors could at any subsequent point dictate that the candidate compound cannot become a commercial product.

# (NOT CONTROVERTED).

23. For the next two to four years, technical managers involved with the candidate compound are faced with the fact that the few compounds surviving the first stages of testing, each representing an intensive effort involving hundreds of man years and millions of dollars of expenditures, must be thoroughly evaluated in order that they can be commercialized safely and efficiently. On the other hand, every additional year that any of these compounds is tested increases the cost of studying that compound exponentially. If the difficult decision to reject a compound early is not made, the cost accelerates and, more importantly, valuable scientific resources will be wasted pursuing a loser rather than a winner.

# (NOT CONTROVERTED).

24. The same difficult decisions must be made as to the expanded process engineering which is initiated in order to determine if raw materials are available, if appropriate large-scale synthesis methods can be divised, if it is possible to produce the product in compliance with the various federal and state regulations dealing with manufacturing safety, discharges of waste, discharges of effluents, emissions of air pollutants, and proper industrial hygiene. Ac-

cordingly, long before plaintiff knows whether it has a successful product, its management must commit further millions of dollars to build a plant for manufacturing commercial quantities of the product according to a chemical process which has not yet been proven on large scale, and to produce a compound whose environmental and toxicological characteristics have not yet been finally determined and for which the necessary approvals by defendant to sell will not issue for 5 to 9 years. If commitments to resolve these problems are not made long before definite answers are available, any of these problems could become a limiting factor and delay the commercialization of a compound for several years.

(NOT CONTROVERTED).

26. It is plaintiff's experience that the initial registration of a new pesticide under FIFRA is usually limited to one or a few important uses of the chemical. Further commercial experience with the compound, together with technical data from continued research and experimentation, may result in new ways of utilizing the chemical. Each of these new or expanded uses must be registered under FIFRA. A great deal of plaintiff's research and development activities are directed to expanding the registered uses of its products. These expanded uses can represent a substantial portion of the market potential of the compound. A substantial part of the effort discussed in connection with the development of a new pesticide must be repeated for each succeeding new use. For example, plaintiff's Lasso herbicide was initially registered only for applications to the surface of the soil, mixed in water, for corn and soybeans. Since then, plaintiff has expanded its registration for Lasso under FIFRA to permit its use in up to 200 different ways on corn, soybeans, peanuts, dry beans and a substantial number of other crops. These expanded uses represent most of the present commerical value of Lasso and, in addition, represent more than 60% of the total research and development effort which plaintiff has invested in Lasso. Plaintiff identified the target for which Lasso was developed in the mid-1950's, obtained its initial registration for Lasso in 1969, obtained U.S. Patent No. 3442945 covering the compound in 1969, and in 1979 still has substantial research committed to a number of major expanded uses. These various expanded label changes each require from two to six years of research and development in order to complete the requirements for registration established under FIFRA. In many cases, plaintiff is now using methodology, techniques, protocols and equipment that were not even available when Lasso was first marketed, and many of which were developed by plaintiffs specifically to expand the potential uses of Lasso.

## (AGREED).

27. In order to support the registration of its products under FIFRA, plaintiff submits to defendant, information, research and test data of the following types: (1) efficacy studies; (2) phytotoxicity studies; (3) metabolism and residue studies; (4) environmental chemistry studies; (5) toxicology studies; (6) fish and wildlife studies; and (7) manufacturing studies and information.

## (AGREED).

28. Plaintiff's efficacy testing begins with the application of the pesticide to very small plots under rigorous conditions to determine answers to limited and specific questions. These small plot studies are continued over a number of years. The small plot testing evolves to large scale field tests using farm equipment, under actual farm conditions. An important factor in the commercial success of any pesticide is not only performance under a given set of conditions, but also its consistency of performance over a wide range of conditions. To determine performance consistency, many trials and experiments must be conducted to understand fully the biological properties of the compound under the widest possible range of conditions. Efficacy testing is utilized to determine and assess all possible argicultural and non-agricul-

tural uses of the product, the target species which are controlled or modified, and the proper rates, methods, time, site, and biological effects of application of the product. This information obtained from efficacy tests is used to devise the most effective methods of use by the farmer under the widest range of conditions.

### (AGREED).

29. In plaintiff's phytotoxicity testing, it conducts many trials in the greenhouse as well as in the field to determine the safety of the chemical, not only to the crop for which it is intended, but also to adjacent crops and other vegetation which may receive drift particles from the spray of the pesticide, and to crops which may be planted in succeeding years in the same field on which the pesticide was applied. In the development of plaintiff's pesticides, scientists in different areas of the United States conduct experiments on the most sensitive crops in their general area. They apply the pesticide being tested in very small amounts and in different concentrations to simulate drift to these sensitive crops at different times in their development. These crops are then grown to maturity and measurements of quality as well as yield are made to determine what, if anything, would happen to the crops if they were exposed to the pesticide at any time during the growing season. Plaintiff also plants a substantial number of rotational crops in areas where the pesticide is to be used to demonstrate that succeeding crops will not be harmed by any residues of the pesticide applied to the previous crops. All such field experiments extend over several years.

# (AGREED).

30. Plaintiff's metabolism studies are conducted to determine what happens to the compound after it is applied. These studies identify and quantify the chemicals into which the compound is converted and establish the sequence of this conversion. These other chemicals, generally referred to as alteration products, include metabolites which result from the processes of a living organism

upon the pesticide, and degradation products which result from the effects of sunlight and water upon the pesticide. Plaintiff must determine these metabolic and degradation products in the context of the extraordinarily complex bio-chemistry which is characteristic of living things.

(AGREED).

31. To effectively study the metabolic and degradation products, plaintiff employs the use of radiolabeled pesticide compounds which must be synthesized by plaintiff. Radiosynthesis is a special kind of organic synthesis of a pesticide molecule by which known quantities of radioactive atoms are placed at selected points in the pesticide molecule for the purpose of tracing the molecule. Radiocarbon used in radiosynthesis costs \$5,000 to \$20,000 for each pesticide sample. Because of the expense of this process, microchemistry must be used and the radiosynthesis route must be much more efficient than a typical chemical synthesis route in order to achieve the maximum yield of radiolabeled pesticide molecules.

(AGREED).

33. In conducting metabolism studies on plants, plaintiff applies the radioactive parent compound by treating the foliage or the soil and collects samples at appropriate intervals. Thereafter, the metabolic and degradation products of the parent compound must be extracted from the plant with organic solvents. These extracts are subjected to a complex series of separation, isolation and purification processes to isolate the metabolites in sufficient purity and quantity for instrumental analysis to gain information about the structure of each metabolite. The structure of the metabolite must then be confirmed by synthesizing it in the laboratory and comparing it with the material isolated from the extracts. Similarly complex studies are conducted with respect to animal and soil metabolism.

(AGREED).

34. In its residue analysis research, plaintiff studies the remnants of the pesticide previously applied, either changed or unchanged from the parent compound. These residues can appear throughout the environment, dependent upon the characteristics of the pesticide. The purpose of the residue analysis is to determine how rapidly the pesticide applied to a crop is dissipated as the plant matures and how much of the pesticide is present in the harvested corp. In conducting these residue studies on plants, one acre test plots are located in those regions of the country in which the plant to be studied is grown. The plant is raised according to good agricultural practices and the pesticide is applied to it in the manner which would be recommended as the normal use pattern of the pesticide on the plant. The plant is grown to maturity, and samples are periodically taken after application of the pesticide and when the crop is harvested. Climatic and environmental conditions which may affect the residues of the pesticide such as rainfall, soil temperature, air temperature, and other chemicals applied to the plant are measured as the plant matures. The collected samples are analyzed by a multifaceted, chemical residue analytical method. This method includes extraction techniques. clean-up procedures to purify and isolate the extracted pesticide residue from the natural products occurring in plants, and qualitative and quantitative identification of the pesticide residue by detection techniques such as gas chromatography. Different analytical techniques must be used depending upon the characteristics of the plant to which the pesticide has been applied. All residue analyses are based upon the development of complex analytical methodology capable of detecting residues of a level as low as one part-per-billion. Extraordinarily sensitive equipment and highly trained individuals are essential in applying the extremely refined techniques used in the residue analyses.

(AGREED).

35. When the pesticide is to be applied to crops which will be consumed by animals, plaintiff conducts metabolism and residue analysis studies to determine what remnants of the pesticide will be in the tissues of the animals and in the animal products, such as milk and eggs. When the pesticide is to be applied to crops which may be rotated with other crops, plaintiff conducts metabolism and residue analysis studies to determine whether any residues of the pesticide applied to the initial crops will appear in the subsequent crops. Plaintiff also conducts numerous residue analysis related tests including interference studies to assure that the residue analytical methods for its compounds are not interfered with or distorted by the presence of other pesticides or by natural products; stability studies to determine whether the pesticide residue samples remain stable during freezing or other storage while awaiting analysis; and studies to evaluate the effect of commercial food processing upon residues of its pesticides in or on raw agricultural commodities.

## (AGREED).

- 36. Plaintiff's metabolism and residue studies which it has submitted to defendant in support of the registration of some of its pesticide products include:
  - (1) Radiosyntheses and <sup>13</sup>C studies rating to the synthesis of the <sup>13</sup>C and <sup>14</sup>C—labeled parent compound and metabolites.
  - (2) Plant metabolism studies conducted with the <sup>13</sup> C and <sup>14</sup> C parent compound.
  - (3) Standard and confirmatory residue analytical methods relating to residues in plants.
  - (4) Interference studies to determine that the presence of other pesticides or natural products does not interfere with standard residue analytical methods for plants.
  - (5) Stability studies relating to plant residues to determine that samples for analysis remain stable in frozen or other storage pending analysis.

- (6) Residue analysis studies relating to fodder and feeds.
- (7) Studies relating to the effects of commercial processing on residues in foods, fodder and feeds.

(AGREED).

37. In its environmental chemistry research, plaintiff determines the degradation of its pesticides in soil, water and air and the movement of the pesticide on or in soil as the result of rainfall or irrigation.

(AGREED).

38. In this environmental chemistry area, plaintiff conducts water stability studies to determine what transformations occur to the pesticide if it should enter a body of water. These studies are conducted with sterilized water under various conditions of temperature and pH to simulate that which might be found in the environment for the purposes of determining whether and what hydrolysis products may be formed by action of the water upon the pesticide molecule. Studies are then conducted by plaintiff with pond water containing microorganisms to determine what metabolites are formed as a result of the activity of the microorganisms upon that pesticide. As in plaintiff's metabolism studies, these pond water studies are conducted with 13 C and 14 C molecules and involve sampling at regular intervals, followed by the extraction. separation, isolation, and purification and the identification of metabolites.

(AGREED).

39. To determine whether radiation from sunlight transforms the pesticide compound into other chemicals, plaintiff introduces the <sup>13</sup>C and <sup>14</sup>C pesticide compound onto soil surfaces and into water and air, and radiates it with artificial light resembling sunlight. Any resultant chemicals are then extracted, separated, isolated, purified and identified in the same manner as the degradation products and metabolites in plaintiff's metabolism studies.

40. Plaintiff also conducts soil runoff and leaching studies, the former to determine the lateral movement of the compound across the soil surface both in amount an distance, and the latter to determine the movement of the compound down into the soil strata.

#### (AGREED).

- 41. Plaintiff's environmental chemistry studies which it has submitted to defendant in support of the registration of some of its pesticide products include:
  - (1) Studies conducted with the formulated product relating to its soil run-off characteristics.
  - (2) Studies conducted with the <sup>13</sup>C and <sup>14</sup>C parent compound relating to its soil leaching characteristics.
  - (3) Studies conducted with either the parent compound or the <sup>13</sup>C and <sup>14</sup>C parent compound relating to degradation in pond water.
  - (4) Studies conducted with the parent compound relating to effects on soil microorganisms.
  - (5) Studies conducted with the <sup>13</sup>C and <sup>14</sup>C parent compound relating to degradation by photodecomposition.
    - (6) Residue analysis studies relating to soils.
  - (7) Stability studies relating to the parent compound in water.
    - (8) Residue analysis studies relating to water.
  - (9) Standard and confirmatory residue analytical methods for soils.
  - (10) Standard and confirmatory residue analytical methods for water.

## (AGREED).

42. Plaintiff's toxicology tests are designed to determine the toxic properties of its pesticides, and their effects on or in biological systems. These studies vary in length of time, test animals used, and purpose. They are multi-disciplinary studies which bridge the sciences of biology and chemistry. The ultimate purpose of these tests is to establish the point at which the compound being studied has no adverse effects.

43. Prior to commencing its toxicology studies, plaintiff must develop an analytical method to evaluate the stability of the compound in the food to be fed to test animals. It is essential to know whether the compound being studied is stable in food and how long it will remain in the food in order to assure that the experimental animals are consuming the intended doses of the compound. Plaintiff must develop such analytical methods for each of its pesticides.

### (AGREED).

44. Plaintiff's subchronic feeding studies are utilized to determine short-term toxic effects and the range of dosage levels to be used in its subsequent long-term toxicology studies. These subchronic studies generally involve the exposure of the test animals to the compound being studied for less than one-half of their lifetime. These tests provide the preliminary data essential for designing plaintiff's chronic toxicology studies.

#### (AGREED).

45. Plaintiff's chronic feeding studies on dogs measure the effects of the compound upon the animals. These studies are conducted with different groups of animals, each group being administered different dosages of the compound in order to determine the chronic toxicology of the compound over a wide range of exposure. Food intake, body weight, effects on blood, urine, and general systemic effects, are measured throughout the period during which these tests are conducted. At completion, each animal is sacrificed, necropsy performed and histopathological examinations of the tissues and organs are conducted.

# (AGREED).

46. Plaintiff's chronic feeding studies on rats and mice determine whether the compound induces or causes cancer or other tumor development and whether there are other toxic manifestations in the test animals.

47. Plaintiff's three-generation breeding studies determine the effects of the compound upon the reproduction potential of the animals, as well as other effects on the number of young produced, their size and longevity, and birth defects. In these studies the compound is administered to male and female rats beginning in prepuberty. The animals are then raised to maturity and mated, and the compound is then administered to their offspring which are again raised and mated. This process is continued through three generations.

### (AGREED).

48. Teratogenic studies are also conducted by plaintiff to determine whether the pesticide has any effects on the development of the fetuses of pregnant females, and mutagenic studies to evaluate whether the pesticide has any genetic effects which may be passed on to future generations.

- 49. Plaintiff's toxicology studies which it has submitted to defendant in support of the registration of some of its pesticide products include:
  - (1) Acute oral LD-50 studies conducted on the rat and the rabbit with the technical product.
  - (2) Acute dermal LD-50 studies conducted on the rat and the rabbit with the technical product.
  - (3) Acute neurotoxicity studies conducted on the hen with the technical product.
  - (4) Acute inhalation LC-50 studies conducted on the rat with the technical product.
  - (5) Skin sensitization studies conducted on the guinea pig with the technical product.
  - (6) Dermal irritation studies conducted on the rabbit with the technical product.
  - (7) Eye irritation studies conducted on the rabbit with the technical product.
  - (8) Acute dermal LD-50 studies conducted on the rabbit with the technical product.

- (9) Intraperitoneal LD-50 studies conducted on the rat with the technical product.
- (10) Acute oral LD-50 studies on the rat conducted with the metabolites of and impurities in the technical product.
- (11) Subacute dermal studies conducted on the rabbit with the formulated product.
- (12) Subacute inhalation studies conducted on the rat with the formulated product.
- (13) Subacute neurotoxicity studies conducted on the hen with the technical product.
- (14) Acute oral LD-50 studies conducted on the rat with the formulated product.
- (15) Acute dermal LD-50 studies conducted on the rabbit with the formulated product.
- (16) Acute inhalation LC-50 studies conducted on the rat with the formulated product.
- (17) Dermal irritation studies conducted on the rabbit with the formulated product.
- (18) Eye irritation studies conducted on the rabbit with the formulated products.
- (19) Studies relating to residue methods for measuring the parent compound in feeds and evaluating the stability of the parent compound in feeds.
- (20) Subchronic oral rat feeding studies conducted with the technical product.
- (21) Subchronic oral dog feeding studies conducted with the technical product.
- (22) Chronic and oncogenic oral rat feeding studies conducted with the technical product.
- (23) Chronic and oral dog feeding studies conducted with the technical product.
- (24) Chronic and oncogenic oral mouse feeding studies conducted with the technical product.
- (25) Three-generation rat breeding studies conducted with the technical product.
- (26) Subacute inhalation studies on the rat conducted with the technical product.

- (27) Teratogenic studies conducted on rats and rabbits with the technical product.
- (28) Mutagenic studies conducted on the mouse and microorganisms with the technical product.

### (AGREED).

50. In its fish and wildlife research, plaintiff conducts numerous studies to determine the effects of its products upon these species. These include bio-accumulation studies conducted with the radioactive parent compound to determine if the pesticide accumulates in the tissue of fish, and studies conducted with the formulated product to determine its effects upon birds under conditions of normal agricultural use.

- 51. Plaintiff's fish and wildlife studies which it has submitted to defendant in support of the registration of some of its pesticide products include:
  - (1) Acute oral LD-50 studies conducted on quail with the technical product.
  - (2) Acute oral LD-50 studies conducted on ducks with the technical product.
  - (3) 96-hour LC-50 studies conducted on bluegill with the technical product.
  - (4) 96-hour LC-50 studies conducted on trout with the technical product.
  - (5) Oral LC-50 studies conducted on quail with the technical product.
  - (6) Oral LC-50 studies conducted on ducks with the technical product.
  - (7) 96-hour LC-50 studies conducted on bluegill with the formulated product.
  - (8) 96-hour LC-50 studies conducted on trout with the formulated product.
  - (9) 96-hour LC-50 studies conducted on aquatic invertebrates with the formulated product.
  - (10) Bioaccumulation studies conducted on fish with the radioactive parent compound.

- (11) Simulated field studies conducted on birds with the formulated product.
- (12) Reproduction studies conducted with mallard ducks.
- (13) Reproductive life-cycle studies on flathead minnows with the technical product.
- (14) LC-50 studies on marine and freshwater organisms.

(AGREED).

53. Much of the information, research and test data submitted by plaintiff to the EPA under FIFRA is and has been confidentially maintained by plaintiff, and stringent security measures are taken to preserve its secrecy. Much of this information, research and test data has never been disclosed by plaintiff except to the EPA and to other governmental agencies pursuant to their regulatory requirements. The information, research and test data is kept in a Technical Reports Library which is continuously supervised during business hours and locked during non-business hours. The circulation of these reports among plaintiff's personnel is on a limited need-to-know basis and the circulated reports are maintained under lock and key. Plaintiff's personnel execute confidentiality agreements respecting this information, research and test data. Plaintiff's Agricultural Research Department has extensive security systems, including guards providing twenty-four hour around the clock protection. Much of plaintiff's information, research and test data has been computerized to facilitate rapid retrieval and research. This computerized data can be accessed only by plaintiff's agricultural Research and Development personnel, and most of them can only access those limited portions of the data which are relevant to their areas of endeavor.

(AGREED).

54. Before any information, research and test data compiled or developed by plaintiff may be disclosed to outsiders, including plaintiff's personnel who are not engaged in agricultural research and development, it is first carefully reviewed and assessed at three different levels of plaintiff's Agricultural Research Department, including the director of such department, and plaintiff's counsel, to assure that plaintiff's confidential commercial information and trade secrets are not disclosed.

(AGREED).

58. Development of plaintiff's information, research and test data by a competitor would be extremely difficult, if at all possible, and in any event would require the exercise of highly sophisticated scientific expertise and ingenuity for thousands of man-years as well as the expenditure of enormous sums of money.

(AGREED).

71. Much of plaintiff's information, research and test data that it has submitted under FIFRA to EPA and its predecessor agencies contains or relates to trade secrets as defined by the Restatement of Torts and confidential, commercial information.

(AGREED).

72. Plaintiff has certain property rights in its information, research and test date.

(AGREED).

77. Defendant now has pending before her applications for registration submitted by plaintiff's competitors which will require defendant to use plaintiff's information, research and test date in order to grant them. Unless the relief sought by plaintiff is granted, defendant will use plaintiff's valuable information, research and test data, including information, research and test date which is or contains trade secrets and confidential commercial information to grant these registrations as provided by Section 3(c)(1)(D) of FIFRA and, thereafter, will disclose such information, research and test data to members of the public as provided by FIFRA Section 10, and to the extent

authorized by FIFRA Section 10 to any foreign government, including the Soviet Union and the Eastern Block countries.

(NOT CONTROVERTED).

/S/ W. Wayne Withers, W. WAYNE WITHERS,

Monsanto Company, 800 North Lindbergh Blvd., St. Louis, Missouri 63166, (314) 600-2851.

LATHROP, KOONTZ, RIGHTER, CLAGETT & NOR-QUIST,

> /S/ Gary S. Dyer GARY S. DYER.

/S/ C. David Barrier C. David Barrier,

2600 Mutual Benefit Life Building, 2345 Grand Avenue, Kansas City, Missouri 64108, (816) 842– 0820.

COBURN, CROFT & PUTZELL,

/S/ Kenneth R. Heineman Kenneth R. Heineman, Suite 2900, One Mercantile Center, St. Louis, Missouri 63101, (314) 621-8575, Counsel for Plaintiff.

Certificate of Service Omitted in Printing.

#### Plaintiff's Exhibit 41

[Testimony from Mobay Chemical Corp. v. Costle, W.D.] Pa. C.A. No. 79-591]

[3710] GEORGE G. ROHWER, called as a witness in rebuttal by the plaintiff, being first duly sworn, testified as follows:

#### DIRECT EXAMINATION

[By Counsel For Plaintiff, Mr. Jacobson]

[3711] Q. What has been your work experience since your graduation in 1938?

A. I had some temporary jobs, if you want those, but basically in charge of a ranch for a short period of time, worked for the Forest Service for a short period of time, worked in a clothing store for a short period of time.

In 1940 I joined the Department of Agriculture at Gulfport, Mississippi and have worked with the Department of Agriculture since 1940 to the present in various aspects of pesticide control, basically, varied in my responsibilities, of course, through the years.

Q. So, in essence, you have been with the USDA for the past 40 years.

A. Yes, sir.

[3712] Q. Now, you have before you Defendant's Exhibit 2, I believe, which has been identified as a chart of the Pesticide Regulation Division of the USDA. Do you recognize that chart?

A. Yes, sir.

Q. And there is a G. G. Rohwer shown in the top box as I believe it is Acting Director, or is it Director?

A. That is right, Acting Director.

Q. Of the Pesticide Regulation Division. Are you that Mr. Rohwer?

A. Yes, sir.

Q. Would you tell the Court when you came to the Pesticide Regulation Division?

A. Well, I didn't bring my employment record with me, but it was when Dr. Hays left. I was asked to head that division. It was transferred to EPA in I think December of 1970.

Anyway, when it went to EPA, I elected to stay with the Department of Agriculture, so I was there about a year.

Q. So you immediately followed Dr. Hays as Director of the division?

A. Yes.

Q. Now, during the time that you were Director of the Pesticide Regulation Division, did you understand that there was a policy with respect to the use of a company's confidential [3713] data to support the registration of another company's products?

A. I did.

Q. Would you tell us what that policy was?

A. The policy was simply as stated by Dr. Hays, that we considered data of two types; that is, data which was public information, published information, which included for some of the older pesticides a lot of toxicological data that was developed during the War and shortly thereafter for such materials as DDT, and then confidential data, which was the properly of the registrant, whoever that might be.

Q. And in terms of this data that you have identified, would it have been in accordance with the policy or against your policy for a data reviewer to use that to support a second company's application without consent?

A. The policy that was established by Dr. Hays during his tenure was not changed during the time I was there. Confidential data of the company was their data. Public data was readily used by any for registration.

Q. And when you say it was "their data," I take it you mean it would not be used without consent?

A. That is correct.

Q. An if during your tenure as Director such an act did occur, was it done without your knowledge or consent and contrary to the policy as you understood it?

A. That is correct.

### Plaintiff's Exhibit 44

[Deposition from *Dow Chemical Co.* v. Costle, E.D. Mich C.A. No. 76-10087]

[1] CIPRIANO CUETO, JR., having been called as a witness by Counsel for the Plaintiff, was duly sworn by the Notary Public, and was then examined and testified as follows:

#### EXAMINATION BY COUNSEL FOR THE PLAINTIFF

By Mr. JACOBSON:

[8] Q. Okay. Doctor, it is primarily the period of time from 1969 to 1972 that we are interested in here today—that was the time of your employment as the Chief Staff Officer for Human Safety with USDA and then EPA. It that correct?

A. That's correct.

Q. Okay. And as Chief Staff Officer, what were the nature of your duties in that position?

A. Well, I guided the efforts of a staff of about 15 to 20 people, as I remember, and each with responsibilities in various areas of chemicals—such as, some in herbicides, some in instecticides, some in disinfectants.

The primary review involved not only human safety, but involved at that time the fish and wild life as it was referred to. But that responsibility I delegated to someone else and concentrated primarily on the human safety evaluation.

I gave guidance in terms of evaluating the data. [9] I gave guidance in terms of evaluating labels and seeing that the labels actually distilled from the data the information—the toxicological information, and presented it in such a way that the label was most easily understood and reflected the precautions that should be taken.

I also was involved in attempting to develop guidelines, which at that time were rather limited in terms of the actual testing itself that was needed for the toxicological information required for registration.

The duties were primarily in keeping up with the toxicological aspects, chronic, acute, sub-acute or sub-chronic effects a chemical may have.

[11] Q. Okay. I'll try to make clear in any of my questions now when I refer to data, as to whether I'm referring to company data—that which was generated and submitted by a particular company—and the other kinds of data we have referred to—the public literature data and government data.

With respect to what I will call company data, how was that data treated by you and the people working under you in the Human Safety Staff?

A. It was handled as confidential material. In fact, we were supposed to lock the material up, which we did, at the end of the day. It was maintained, except for the working material that we were handling at that particular time—it was kept in locked files.

[12] The material we were handling at the time was put away in our desk, or finally, I had a safe in my office that this material was put into.

Q. Okay. That would be with respect to maintaining the confidentiality of it within your branch, so that other people who would not be authorized to look at it, I take it, would not have it available. Is that correct?

A. That's correct.

Q. Okay. Then, did you have the situation in which company data would be used without permission to support the registration application of another registrant?

A. Not that I am aware of. This was not the policy. The data was used exclusively for the registration for which it was submitted. It was also used for other registrations if the data had been generated by that particular registrant.

There were data that might be considered for purposes of registration. Such data was that which was already in the literature, already quite widely circulated, and so, therefore, one could draw on that data.

We also what was referred to as "old interpretation 18", which contained, actually, a summation of information based on toxicological data for certain [13] compounds that had extensive formulations registered. And, therefore, one could even—from the interpretation 18—wind up with a particular type of label requirement based on the toxicological information that was accepted under interpretation 18.

- [19] Q. With no—maybe I should add, without permission. Was it a situation that you are familiar with that occurred within your staff, where they would use one company's data in support of another company's application without permission?
- [20] A. Not to my knowledge. If that had occurred, that would have been, I consider, one of my responsibilities in stopping that sort of thing. The data that was submitted by the applicant was the data to be reviewed, and other data could be reviewed if the applicant had obtained permission for that data to be used. And we had a written statement that such action could be taken.
- Q. Okay. And was it your understanding that the policy of the Pesticides Regulation Division was that such a use should not occur?
  - A. I'm sorry?
- Q. Was it your understanding that the policy of the Pesticide Regulation Division was that such a use without permission of the other company should not occur?
  - A. That's correct.

### Defendant's Exhibit P

MAY 22, 1970.

Mr. B. J. CARCEAU, ICI America Inc. 151 South Street Stamford, Connecticut 06904

DEAR MR. CARCEAU: This is in reply to your letter of May 8, concerning the development of a new alimicide product.

Efficacy data and toxicological data would be required on a new formulation. Since you did not furnish us the details of your proposed product, it is impossible to state what the exact requirements would be. If adequate data is on hand for a formulation further data is not needed.

Until we receive the complete formula and the proposed labeling for a product, we cannot determine the precise data needs to support registration.

Sincerely,

HAROLD G. ALFORD,
Assistant Director for Registration.

[Airmail]

# [DEFENDANT'S EXHIBIT Q]

Environmental Protection Agency, Pesticides Regulation Division, Washington, D.C., Mar. 1, 1971.

Mr. J. Hattori, Sumitomo Chemical Company, Ltd., 15 5-Chome, Kitahama, Higashi-Ku, Oska, Japan

DEAR MR. HATTORI: This is in reply to your letter of February 22, 1971, which has been referred to me by Mr. S. A. Hall of the Entomology Research Division.

Enclosed is a registrant's kit which contains copies of the Federal Insecticide, Fungicides, and Rodenticide Act and all pertinent regulations and interpretations of that Act. Also enclosed are copies of the forms necessary to apply for registration of an economic poison. It is difficult to answer question number 6 in your letter without knowing the specific compound you are interested in registering. If it is a pesticide that is well-known and for which this Division has toxicological and efficacy data on hand, such data would not be required to be submitted. However, if you are interested in registering an unknown chemical, data will be necessary to show that the product is safe and effective when used as directed.

Sincerely,

T. E. ADAMCZYK, Chief, Registration Branch.

Enclosure: Registration Kit.

[DEFENDANT'S EXHIBIT R]

Pesticides Regulation Division, November 16, 1971.

Wasatch Chemical Company Post Office Box 6219 Salt Lake City, Utah 8106 Attention: Mr. John Walrer.

This is in reference to our recent telephone conference regarding compounds whose patents have expired.

The Federal Insecticide, Fungicide, and Rodenticide Act, states that a product must be proven safe and effective when used as directed and that the burden of proof is on the registrant. However, once this Division receives and accepts such data for a particular compound, other registrants may, for other than disinfectant-type products, register that compound without the necessity of repeating efficacy and toxicity testing. The foregoing assumes, of course, that the subsequent formulation are essentially identical to the product originally registered and that the use patterns are the same.

It should be pointed out that H.R. 10729, the new pesticides bill recently reported out of the House Agriculture Committee, contains a provision that data submitted in support of a registration may not, without the original

applicants permission, be used in support of any other registration. If and when the new legislation is enacted, each registrant will be required to develop his own data. Sincerely,

T. E. ADAMCZYK Chief, Fungicide-Herbicide Branch.

[Defendant's Exhibit S]
Pesticides Regulation Division,

January 12, 1972.

Mr. J. J. LENZOTTI, The Sherwin-Williams Company 101 Prospect Avenue, N.W. Cleveland, Ohio 44101

DEAR MR. LENZOTTI: This is in reply to your letter of December 21, 1971, concerning requirements for registration of a fungicide.

It is impossible to state precisely what information will be required for your proposed product since we have no way of knowing what claims you intend to make, nor do we know the precise formulation of the product. In general, however, if the product is precisely identical to that product by Rohm & Haas and the claims and directions for the product are the same, no efficacy or toxicity data will be required in support of the registration. If, however, your formulation differs in any way or you intend to make additional claims, efficacy and toxicity data may be required to support registration.

Enclosed are copies of forms for new registration. Please note that this Division requires five copies of your complete formula including the percentage of active and inert ingredients by weight. If you do not have this information, you must request your basic supplier to contact this Division with regard to granting permission to use their file in support of your application.

Sincerely,

T. E. ADAMCZYK, Chief, Fungicide-Herbicide Branch.

Enclosures.

# [DEFENDANT'S EXHIBIT T]

Pesticides Regulation Division, September 29, 1972.

Mr. John E. Gee, 250 Delaware Avenue, Apollo Chemical Corporation, Clifton, New Jersey 07014.

DEAR MR. GEE: This is in reply to your letter of September 18, 1972, regarding registration procedures for a proposed microbiocide product.

To obtain registration it is not necessary to submit a sample of your proposed formulation. Please submit five copies of your proposed label as well as five copies of your complete formula, including the percentage by weight of each active and inert ingredient. Enclosed are several new registration forms. If you will refer to the reverse side of these forms, you will note complete instructions on filing for registration.

Concerning required data, if your product is sustantially identical to other products registered with this Agency, it will not be necessary to submit toxicity or efficacy information. However, if your product is unique or if your proposed patterns of use and dosages differ from those previously accepted, we may require toxicity and efficacy data.

Sincerely,

T. E. ADAMCZYK, Chief, Fungicide-Herbicide Branch.

Enclosure

# [DEFENDANT'S EXHIBIT H H]

NATIONAL AGRICULTURAL CHEMICALS ASSOCIATION, MEETING OF BOARD OF DIRECTORS, PAUMA VALLEY, CALIFORNIA, APRIL 25, 1970

#### Minutes

# Time and place

A meeting of the Board of Directors was held on Saturday, April 25, 1970, at the Pauma Valley Country Club, Pauma Valley, California at 8:30 A.M.

### Attendance

Members Present:

Richard H. Wellman, Chairman—Union Carbide Corporation

James G. Affleck—American Cyanamid Company Charles O. Barnard—Western Agriculturanl Chemicals Association

Parke C. Brinkley-NAC Association

Jack G. Copeland, Jr.—Hercules Incorporated

K. Ross Fitzsimmons—Shell Chemical Company

Edward K. Hertel—Niagara Chemical Division FMC Corporation

Robert J. Hoffman—Miller Chemical Company, Inc.

Charles L. Hovey-Agway, Inc.

Harold H. Howard—Thompson-Hayward Chemical Company

Carlos Kampmeier—Rohm and Haas Company Edward J. Korbel—Allied Chemical Corporation Frank McGrane—Western Agricultural Chemicals Association

Robert M. Morris—Velsicol Chemical Corporation

Robert E. Naegele—The Dow Chemical Company

Frank B. Stewart-W. R. Grace & Co.

Herbert F. Tomasek-Chemagro Corporation

J. Drake Watson—Pennwalt Corporation

Members Absent:

T. W. Cleveland, Sr.—Woolfolk Chemical Works, Ltd.

J. Paul Ekberg-Tenneco Chemicals, Inc.

A. Malcolm McVie—Elanco Products Company Div. of Eli Lilly and Company

Otto Sturzenegger—Geigy Agricultural Chemicals Div. of Geigy Chemical Corp.

Others Present:

James C. Hansen, Chairman of Public Relations Committee (part time)—The Dow Chemical Company

# [7] Naegele Committee Report

(a) Confidentiality of Registration Data.—[8] The Board discussed the proposed letter to the Secretaries of Agriculture, Health, Education, and Welfare, and Interior which appears at pages 13-16 of the supplementary material to the agenda. Mr. Hertel reported that the Policy Advisory Committee, after reviewing the proposed letter, adopted the following resolution:

RESOLVED, That the Policy Advisory Committee recommends to the Board of Directors that the proposals of the Naegele Committee, as set forth at pages 14-17 of the supplementary material to the Agenda, be adopted by the Board of Directors with the proviso that the recommendations of NACRAC that the proposal be referred to the NAC Lawyers Committee for study be followed.

In the discussion of the proposal, it was the consensus that the proposal that research work conducted on one pesticide compound should not be considered in acting upon the registration of another pesticide compound, should not be premised upon a request that such data be considered as confidential but that the proposal more logically is justified on the basis that the biological properties of related or similar pesticide compounds may differ substantially depending upon the method of manufacture. It was suggested that the proposal, as it appears

in quotes at pages 15 and 16 of the supplementary material to the agenda, be changed to read as follows:

We propose that each application to the U.S. Department of Agriculture for a label registration of a pesticide chemical or formulation shall contain full reports of all investigations carried out by or for the applicant to show the safety and efficacy of the pesticide formulation. This includes full reports on investigations submitted in petitions for residue tolerances. With respect to formulations, such reports may be included in a registration application by reference properly authorized by an original registrant.

[11] On the following pages is reproduced a NACRAC working paper and the Naegele Committee proposal for your consideration.

[13] PROPOSED LETTER TO THE THREE SECRETARIES (AG, HEW, INTERIOR)

Subject: Industry incentives.

The pesticide industry is presently operating in a very unfriendly, if not hostile, public climate, Substantial companies have left the field entirely. Many other companies have ceased all research, while others have cut back drastically. Soaring costs coupled with inelastic demands have reduced profitability to dangerous level.

If we are to cooperate fully with the governmental agencies and at the same time provide the products necessary for a healthy, low cost agricultural industry, a definite understanding and alleviation of these problems should be considered. Otherwise, development will grind to a halt in the United States leaving the field to foreign competitors and/or drastically impair the cost and quality of our food supply.

[14] In view of this, we proposed what we felt to be one of the most necessary actions to facilitate industry devel-

opment of less persistent and less hazardous materials to man and his environment. The background is as follows:

# Background

When registration of a pesticide involves use on crops, the manufacturer submits a petition to the USDA and DHEW proposing a residue tolerance on the crop or crops involved. Registrations for non-crop uses are processed by the USDA only. All data submitted are considered confidential by the USDA, DHEW, and any other interested government agency. The research involved in the preparation of these data is by far the largest source of expense in the total research and development process for pesticides. The cost of this work is expected to increase rapidly as additional tests are required to establish ecological safety.

In general, manufacturers do not engage in this development work on new pesticide discoveries unless they are sure of obtaining a strong patent position with the new product. Thus, a relative large number of unpatentable products that are known to have pesticidal activity remain on the shelves of industrial laboratories. Furthermore, the length of time from the discovery of a new product until all of the work necessary for registration is completed, and until registration is obtained, is such that frequently relatively few years of patent life remain. This also makes it less likely that a manufacturer will decide to [15] push ahead with a new pesticide discovery unless it is aimed at a very large market or has a very broad spectrum of activity.

Under present regulations, once a pesticide is registered by the USDA, another applicant with the same product can submit a label identical in ingredient statement, precautionary information, and directions for use. The USDA then issues the second applicant's registration. The submission of data by the second applicant is not required. When DHEW establishes a tolerance for a pesticide residue on a crop or crops, the tolerance becomes public property. Anybody using a particular pesti-

cide, regardless of the source, is free to do so providing that such product and use do not result in a residue greater than the established tolerance.

### Defendant's Exhibit PP

#### AFFIRMATION OF MULTINATIONAL STATUS

Notice to Requesters of information submitted to the Office of Pesticide Programs, EPA, by applicants and registrants under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA)

This affirmation is required pursuant to EPA Interim Procedures that implement Section 10(g) of FIFRA (7 USC 136h(g)). This section is reprinted in part on the reverse side for reference. Since the law specifically prohibits disclosure of information to employees or agents of Foreign and Multinational Pesticide Producers, the purpose of this affirmation is to establish whether the requester is affiliated with such producers. Since affiliations can change, this affirmation will be required of each requester at the time of each request.

I have requested access to information submitted by an applicant or registrant under the Federal Insecticide, Fungicide and Rodenticide Act (7 U.S.C. 136 et seq.) to the Environmental Protection Agency. I hereby affirm:

- (1) that I do not seek access to the information for purposes of delivering it or offering it for sale to any business or other entity engaged in the production, sale, or distribution of pesticides in countries other than the United States or in addition to the United States or its agents or employees; and
- (2) that I will not purposefully deliver or negligently cause the data to be delivered to such business or entity or its agents or employees.

I am aware that I may be subject to criminal penalties under 18 U.S.C. 1001 if I have made any statement of material facts knowing that such statement is false or if I willfully conceal any material fact.

NAME

SIGNATURE

DATE

RIN

Client, if you are requesting access on behalf of someone other than the organization or Affiliation listed above.

### ORGANIZATION

#### ADDRESS

Return this form to: Information Services Branch (TS-757) PSD, Office of Pesticide Programs U.S. Environmental Protection Agency 401 M Street, S.W. Washington, D.C. 20460

## Defendant's Exhibit CCC

[Deposition of Dexter B. Sharp, Ph.D., taken on behalf of the Defendant.]

[70] [By Counsel for Defendant, Mr. McLaughlin:]

Q. Okay. If we can move on to Exhibit No. 11 which describes the simple apparatus and is entitled, "A Simple Apparatus and Quantitative Method for Determining the Persistence of Pesticides in Soil." Are you familiar with this paper?

A. Yes.

Q. And in this paper it describes a technique relying a carbon 14 labelling, again, of Roundup to determine the degradation of Roundup in soil, is that correct?

A. Yes. That was used as an example. You will notice we also have CDAA and Diallate as a part of this paper, a couple of our older compounds. The reason this paper was published was to, first of all, appropriate a [71] procedure to the scientific procedure—scientific community which is superior to the guideline directions or recipes for determining being degradation in soil and CO<sub>2</sub> evolution because the citations of the literature that the EPA used in the 1975 guidelines and, indeed, I think—well, the 1975 guidelines were from older literature, were extremely cumbersome, and what we wanted to do in this instance was to acquaint our peers in the scientific community as well as the EPA that, "Look, here's a convenient small concise and precise way to answer a question in regard to pesticides, in general, glyphosate."

## Defendant's Exhibit DDD

[Deposition of JACK DENT EARLY]

[4] JACK DENT EARLY was called as a witness and, having been first duly sworn, was examined and testified as follows:

#### EXAMINATION BY COUNSEL FOR DEFENDANT

By Mr. RAMSEY:

[25] Q. What I'm also interested in, and I think probably what a lot of folks are interested in, is your understanding at the time of the practice of the United States Department of Agriculture in granting registrations to what let's call "Me-Too" registrants. And if I say, "Me-Too" registrants, do you understand what I'm taking about?

A. Yes. If I could clarify that, when you say, "Me-Too," you're talking about a party or a registrant that comes in and gets a subsequent registration on an identical product without permission or without consultation with the original registrant.

Q. That is correct, sir.

A. I'm differentiating that between a number of situations where we in Monsanto at the time would allow a customer who was formulating one of Monsanto's products to utilize our data to register his formulated product.

Q. That's fine.

A. I'd consider that a "Me-Too" situation.

Q. Fine. Let's make that distinction for the record, for the time being anyway.

[26] Were you aware in 1964 or shortly thereafter of the custom and practice of the United States Department of Agriculture in granting "Me-Too" registrations?

A Granting "Me-Too" registrations? I was not aware of any that were being granted at the time, based on our definition of "Me-Too."

- Q. When did you first become aware, if you ever did, that the Department of Agriculture was granting such registrations?
- [27] A. I am not aware of any "Me-Too" registrations that were granted by USDA. And I'm restricting that to USDA. We're talking USDA, aren't we?
- Q. Yes, we are. That is correct. And now I'm not just referring to Monsanto's, to registrations that might be granted that were substantially similar or identical to Monsanto products. I'm talking about you, as the company representative, being generally aware of the overall picture at USDA. You understand that?
  - A. Yes.
- Q. And it's your testimony that you're not personally aware and never became aware that USDA ever issued any "Me-Too" registrations?
- [28] A. Well, I'm not personally aware of any, no.
- Q. Did you ever have any discussions with any other company representatives or USDA employees or other persons during that period of time, in which you were told or led to believe that "Me-Too" registrations of the kind we discussed were being issued?
  - A. I don't recall any such discussions.
- Q. Let's ask the same question for EPA. Were you aware at any time prior to 1972 that the United States Environmental Protection Agency was issuing what we referred to as "Me-Too" registrations.
  - A. Prior to 1972?
  - Q. Yes, sir.
  - A. I'm not aware of anything prior to 1972.
- Q. Are you aware prior to 1972 whether or not USDA or EPA issued registrations to subsequent registrants? In other words, there'd already been a registration granted to some company, and subsequent to the granting of that first registration, another company comes in and seeks to obtain a registration by submitting a label and data which satisfies EPA that the formula of the product for

which they are seeking a registration is identical or similar enough to almost be identical to the product that was previously registered; [29] and those two departments not requiring any further data to grant those registrations?

A. Let me clarify a point here for you, which would, I think, clarify my understanding here.

We've talked about "Me-Too's," based on our definition earlier here. I am talking with respect to "Me-Too's" from the standpoint of proprietary products. And let me clarify that by saying that there were a few commodity products registered with USDA at the time. By this, it's obvious these were products not under any patent coverage, products that had been around for many years, and the number of which had really never been under any patent protection.

I'll use as an example parathion. It was a commodity item and it was also a product that Monsanto manufactured. We had a number of labels for parathion, and other companies also had labels registered for parathion, and from time to time we would seek to upgrade the label by adding new uses or new rates, new methods of application; and it was not uncommon for those commodity products to go in with a label and registration personnel of USDA, if they had accepted that particular rate use on parathion in the past, would accept your label for registration at the same rate on the same insect without requiring additional [30] efficacy data.

So you could upgrade—you get a label like this without supplying data on a commodity.

- Q. When you say "label," you mean "registration."
- A. Registration, yes.
- Q. How is that different in your mind from what we referred to as a "Me-Too" situation?
- A. The "Me-Too" situation—and I think it was a very clear distinction over there in USDA at the time in differentiating between what I call "proprietary" and "commodity" items.

I do not know of anyone who attempted to come in—or if they did, I'm not aware of it—and was successful in getting a "Me-Too" registration for a proprietary product.

Obviously, I can only speak for the Monsanto product line.

[55] Q.

Are you aware of any practice of the Department of Agriculture during your time as Monsanto's company representative in requiring "Me-Too" registrants to obtain the permission of any previous data submitter to use or ask the USDA to use or rely on that data to obtain a "Me-Too" registration?

- A. To register a similar product?
- Q. Yes, sir.
- A. I don't think I am.
- [58] Q. Did you personally, as Monsanto's company representative, or later, as an employee of NACA, play any part in [59] preparing the testimony that was given before Congress in 1971 about the amendments to FIFRA which were enacted in 1972?
- A. Yes, I did. Obviously, that was in the capacity with Monsanto.
  - Q. Yes, sir.
- A. Because at that time I was serving—while still with Monsanto I was serving as the chairman of the NACA Washington Representatives' Committee.
- Q. What were your responsibilities as the chairman of that committee?
- A. In chairing that committee the Association looked to us for input and suggestions on ideas and approaches in the legislative process in our efforts to develop reasonable and fair legislation.
- So I was involved, as chairman of that committee, as part of that process.
- Q. Did that include developing ideas and proposals about exclusive use provisions to be put into FIFRA?
  - A. I was part of that process, yes.

Q. What part? Were you just a member, or were you the chairman of the committee that—

A. I was chairman of the Washington Reps' Committee, [60] but I'm not sure that that provision was an initial thought out of the Washington Representatives' Committee, is what I'm saying. That's eight, nine years ago. I just don't recall.

Q. As you now recall it, what was the reason that NACA and Monsanto—no, let be back up.

As Monsanto's representative at the time, do you recall whether Monsanto favored the exclusive use provision that was subsequently put into the 1972 FIFRA?

A. Yes, I'm sure we did.

#### Defendant's Exhibit FFF

[Deposition of Harry W. Hays Taken in Dow Chemical Co. v. Costle, E.D. Mich. C.A. No. 76-10087.]

#### **EXAMINATION BY COUNSEL FOR PLAINTIFF**

By Mr. JACOBSON:

[6] Q. Okay. In this deposition, Doctor, what we are primarily interested in is your employment experience with the Pesticide Regulation Division of the United States Department of Agriculture.

In that connection, would you indicate how you came to become Director of the Division?

A. Well, it was in 1965, 1965 or very early 1966, that I was asked by the Secretary of Agriculture, Mr. Orville Freeman, if I would be the Chairman of a Task Force to review the activities of the Pesticide Regulation Division, [7] because at that time they were under considerable pressure for improvements, and the Department thought it would be best to appoint a Task Force to take a look at what was taking place.

That committee was formed rather quickly. In a matter of I expect five or six months, maybe a little less, the committee submitted its report to the Administrator of the Agriculture Research Service. and shortly thereafter, I was asked by the Administrator if I would consider taking on the responsibility of being the Director of the Division.

I was then called into Secretary Freeman's office to discuss the possibility of my becoming Director of the Division, and after considerable thought I decided that maybe I could help in reorganizing the Division. So I accepted the offer to become the Director.

[11] Q. Okay. The question, or one of the issues in this lawsuit, Doctor, deals with the treatment of company data [12] by the Pesticide Regulation Division, USDA. And I will separate it into two parts—one dealing with

disclosure and making it available to other people, and the other dealing with use.

First, let me ask you about disclosure. Was the data—company data—let me say confidentially maintained by the Division under your tenure?

A. Well, it was my instruction to the Assistant Director of Registration and to the Assistant Director of Enforcement, that the data that was submitted by the industry was to be considered confidential.

Now, in that light, in addition to the files that we put in under a central file, in order to maintain that integrity of the file and the confidentiality, we also gave each of the reviewers a file, in this case a locked file to keep at his desk where the reviews were being made. And this was totally directed toward maintaining confidentiality.

Q. Okay. Now the other aspect in terms of company data that I want to ask you about, Doctor, and during your time as Director, was a question of use of that data in support of registration applications.

Now, I take it that you would agree that the company [13] who had developed and submitted the data in support of its own registration application, there was no question about the registration—the Regulation Division using that data in the review of their particular application for registration.

- A. That is correct. It was used for their sole purpose.
- Q. Okay. Are you also aware of situations where a company who had developed and submitted data in support of their applications would grant permission to other applicants, or to the Regulation Division for you to use that data in support of an application for registration by another company?
- A. Yes. There were instances when the registrant would permit his data, or her data, to be used for the registration of another product.
- Q. Okay. And that—would that, in your judgment, violate any of the policies that were in effect at that time?

- A. No, provided that in the use of that data we had direct confirmation by the registrant, either by letter or by phone or whatever it may be, that it was permissible for that person, or for us, to use that data to register the product per that person's request.
- [14] Q. Okay. Now, let's take a situation, one in which the Government, or the Defendant has indicated in this case, that it was the regular practice of the Pesticide Regulation Division to use one company's data in support of an application for registration by another company, without permission.

Would any such use have been in accordance with the policy of the Division at the time you were Director?

- A. No, it wouldn't.
- Q. Okay. What would have been the policy with respect to such a use?
- A. Our policy, from the very beginning, was that the data that was—belonged to one individual registrant was not to be used by another unless he had permission.
- [23] Q. Okay. And to your knowledge, if any occasions arose in which company data had been used to support an application for registration of another without permission, would that have been in violation of the policy that you had established as Director?
  - A. It certainly would have.
- [29] EXAMINATION BY COUNSEL FOR THE DEFENDANT
- [51] A. Well, as the Director, I was responsible for setting the policy and instructing the staff as to what the policies would be, of working out difficulties that might arise from day to day in matters of registration or enforcement, working with them to organize and coordinate the activities of the Division, educational programs for

the staff, just regular day-to-day supervision through the directors, assistant directors.

[52] Q. Would it be fair to say, then, that Mr. Alford would be more familiar with the actual day-to-day operations of the registration program then you, yourself, would be as supervisor?

A. I think so-as Director.

- [59] Q. Now, you also stated that it was your policy that one applicant could not rely on data which another applicant had submitted without the first applicant's permission.
  - A. Correct.
- Q. Now, when you are talking about data, are you [60] referring to the confidential statement of formula, or are you referring to all types of data?
- A. I'm referring to the formula, I'm referring to the safety data, and I'm referring to the effectiveness data.
- [65] Q. Now you testified that you had a policy regarding consideration of one person's data in support of another company's application. Do you know whether, in fact, that policy was followed in the day-to-day issuance of registration?
- A. How would I know? I have no idea. I wasn't at every desk day-to-day.
- Q. So the answer is no, you don't know whether it was followed or not.

A. No. That's right.

### DEFENDANT'S EXHIBIT GGG

[Deposition of Cleve A. I. Goring Taken in *Dow Chemical Co.* v. *Gorsuch E.D. Mich.*, C.A. No. 76-10087]

EXAMINATION BY THE COUNSEL FOR DEFENDANT By Ms. Mulkey:

[33] Q. Your counsel have listed you as a witness who will support a finding which they proposed the Judge make, to the effect that the patent protection is difficult and expensive to secu. In a maintain in nations other than the United States.

Could you tell us the comparative patent situation between the United States and other nations?

A. Yes.

Q. To your knowledge?

A. Yes. I have spent a great deal of effort on the question of patents and obtaining valid patents. In fact, that's one of the things I've spent quite a lot of time on.

Patent law, of course, varies in all over the world. Some countries you can't obtain patents in, some countries the patents that you do obtain have really relatively little validity or usefulness. For example, in many of the [34] eastern European countries or Russia they are so specific they don't provide a broad frame of protection. Some countries the patent will last for 15 or 20 years, some countries much shorter period of time. In some countries you have to renew your patent franchise every few years, as you pay fees, and in others you do not, like the United States.

In some countries you basically have to work the patent or it lapses. In other words, if you apply for a patent in Spain, then you have to basically work that patent or sell the product or manufacture it within a period of three years or else the patent lapses. So most people simply don't get patents in Spain because in this kind of product, they can't meet the requirements.

But there's one major difference between the United States and virtually all other countries, virtually all countries in the world, Canada is an exception which I will explain. In the United States the person that gets the patent is the first to invent so that if there is an argument about patentability in the United States, and there's an interference, then the case goes before the Patent Board and a determination is made as to who invented it first. So you go back all the way through the dates of original synthesis, original biological testing. But in the rest of the world the person that gets the patent is the [35] first to file a case, and it doesn't matter whether the first to invent or not. So it becomes extremely important in order to get patent coverage in countries around the world that you file quickly.

Those that don't, don't get patents around the world. And so, I must tell you that in 20 or 30 years ago when most of the U.S. companies basically were conducting pesticide business primarily in the United States, rarely overseas, that they would take their time about filing U.S. patents because they knew the first to invent would get the patent. But as the whole patent-as the whole pesticide arena expanded and the U.S. companies moved overseas and other companies moved into the U.S., and I think approximately 65% of the pesticide business is outside of the U.S., it became very important to file early. And so our present policy, and I believe the policy of virtually every company in the business, is to file their cases as early as possible. This means that even before compounds are in development, patent cases are filed now, and probably will become allowed within a year of being in development.

So we have the problem of a very long time before commercialization, but the necessity to file early in order to obtain the patent coverage around the world.

Q. In other nations you mean now?

[36] A. In other nations, yes. I must say, though, that even if you don't file, if you don't file early in the United

States and you get into an interference, you are at a disadvantage, you are not the first to file, you then are the Plaintiff, you have to prove that the person that was first to file isn't entitled to the patent. He's the Defendant, you're the Plaintiff, so he stands back and shoots at you.

Q. Okay. With respect to the patents in other nations, has Dow ever attempted to correlate its sales volume or profit to its degree of patent protection to determine whether the patent availability and quality of patents has affected its market in other nations?

A. Oh, yes, I think so. You have to have patents in the ag business. You either have—you have to have protected products, one form or another. If you do not, the business is so enormously competitive, that unprotected products are apt to become unprofitable.

Q. Could you name a nation which has no patent protection which is a major agricultural nation?

A. I don't—well, Italy is one which it's very difficult to get significant patent protection.

Q. Does Dow market products in Italy?

A. Oh, yes, and we have imitators.

Q. Has Dow determined that its market share in Italy is [37] significantly different than its market share in, say, France?

A. Well, I—that depends on your ability to market in the countries. But I would say that we certainly have more competition from imitators in Italy prior to the time that our patent protection runs out than in France or Britain or Germany.

For example, on the pesticide Plictran, we had imitators selling Plictran in Italy long before the patents on Plictran ran out in Europe. As soon as the patents run out, you ordinarily on a major pesticide will have imitators producing the product.

Q. In most countries?

A. Yes.

Q. And at purely as soon as the patent runs out?

A. Well, you have the worldwide, when the patents run out you will have it in specific countries where you can't get patent coverage before the patents run out.

Q. Pretty much regardless of any other requirements like registration requirements?

A. Now, that's not necessarily so. And I don't know what the situation is in Italy personally; basically most of the major countries, in fact, virtually all of the major countries currently do not permit imitators to utilize the registration data that a company provides for the [38] registration of pesticides in that country.

Q. I'm having a little trouble reconciling these things that you've just said. I take it the key to the big burst in competition in any nation is when the patent protection in that nation expires, is that what I understood you to say?

A. The big burst in competition is when patent expiration takes place all over the world, and that takes place over a period of, perhaps in the major countries, four or five or six or seven years or so.

# Q. In nations-

A. If you think of the actual time schedule involved, for example, the window in which you have to operate under a protected situation is relatively small. The reason for that is you get your patent early, just about the time you go into development. It may take you six years, seven years before you start to market; certainly six years. Then your registrations are not achieved all at once, but over a period of time so that you may not achieve full registration of your chemical, I don't know, it may be as long as six to 15 years. Your patent runs out 17 years after it's granted, 15 to 20 years.

So frequently you are still obtaining registrations at the time your patent runs out. Then when your patent runs out, basically imitators will attempt to obtain [39] registrations all over the world and produce the chemical at that time.

- Q. And I take it that they've been succeeding and entering into competition against Dow and other companies that held the patents?
  - A. To some extent, to some extent, yes.
- Q. In nations where one or two or three major agricultural companies cultivate the vast bulk of the land, let me, sir, start there. I take it there are nations where that's the case?
  - A. Where what?
- Q. One or two or perhaps three major agricultural companies cultivate the vast bulk of the land, like United Fruit, and in certain Latin American countries, for example.
- A. Oh, I don't think they cultivate the vast bulk of the land, but they are certainly, for specific crops they are—what should I say, they are the major economic force for certain specific crops in that country, yes.
- Q. Okay. Now, does Dow sometimes enter into contracts, exclusive contracts, for sale to such companies so that, for example, Dow would be the sole supplier of a given pesticide to a given major company of the sort we just discussed?
- A. Well, I—I'm not knowledgeable in that area. However, I would guess that those companies don't get into exclusive [40] contracts with anybody, you know, they will purchase their product wherever they can at the lowest price they can.
- Q. Does Dow sell at pretty much the same price world-wide for a given product?
- A. Oh, no. The price of the product that we sell depends on the value of the chemical in the marketplace, if it's possible to obtain that value. If it's not possible to obtain that value, it depends on the competitive forces in the marketplace.

For example, we sell 2,4-D primarily on a competitive basis with other companies in the marketplace. We don't sell it on the basis of its value in the marketplace which far exceeds its selling price simply because there's too much competition. But where you have—where you are protected, when I say protected, where you basically have an opportunity to sell your product without competition from an imitator, you sell it at the value in the market-place or try to sell it based on its value in the market-place.

Now, that does not mean that you are free from competition because agricultural chemical business is an intensely competitive business just from the introduction of new and better products. In fact, I will say that that is where most of the competition comes from, [41] continual introduction of new and better products.

But it does me that you can basically sell your product at what you there is the value in the marketplace rather than selling it at a price that reflects on the competition from imitators that have not had the expenses and the cost and have basically not had to pay the expenses and the cost of developing the product in the first place.

Q. Now, when you say value in the marketplace, do you mean essentially the highest price the market will pay without declining to purchase the product?

A. Yes. And I can tell you what that works out to be because it's—it's a well known measure in the agricultural marketplace. For example, fertilizers are so uniformly accepted by farmers that ordinarily they will pay for—they will expect to receive from their fertilizers in terms of value at least twice of what they paid, so if they expend a dollar on the fertilizer, they will expect to see two dollars in return in terms of production.

Pesticides are not really as well accepted, and so even with a very well accepted pesticide, the farmer would expect to see three dollars of productivity in turn for every dollar expended.

In new products, new developments where the farmer is unsure, the practice is new, he will expect to receive five dollars of productivity in turn for every dollar [42] expended. And if you can provide him with a practice in

which he receives a ten to one return, he will buy it under almost any circumstance.

[57] Q. Okay. So that when one speaks of process research and development, one includes the notion of what kind of tools and assembly line operation and so forth would be designed as well as this category of things contained in that paragraph?

A. Yes. When you talk about process research, what you are talking about is basically all of the research that is needed to indentify the structure and operating conditions of the entire production and waste handling and disposal plan associated with a product, plus the operations to formulate the product, manage it and so on.

Q. Is that fairly complex?

A. Enormously complex, very complex.

Q. It takes a high degree of expertise in order to do that kind of work?

A. Yes, I would say so.

[58] Q.

A. Oh, yes. The production capabilities and experience capabilities of a company are highly dependent on their, what shall I say, their overall collection of knowledge in that area, either in the heads of the people or in company reports, confidential reports, their total experience in that production arena.

Q. And I take it the confidentiality of the research and development associated with process research gives the company an enormous competitive advantage?

A. Well, it gives them a competitive advantage in the sense that it doesn't—the information isn't available to a competitor without doing any work. He can go through the same steps if he's got the capabilities to do so, he can if he puts the energy into it, and is lucky and has good enough people and happens to think along the same directions and is inventive and so on. Presumably he could

come up with the same kinds of information. But the chances are that he would not, not two companies have the same in-house expertise.

### DEFENDANT'S EXHIBIT III

[Testimony of Harry W. Hays from Mobay Chemical Corp. v. Costle, W.D. Pa. C.A. No. 79-591.]

## EXAMINATION BY COUNSEL FOR PLAINTIFF

By Mr. JACOBSON:

[3701] Q. Okay, sir. During your tenure as Director, what was your policy, if there was one, with respect to the use of one company's proprietary data to support the registration application of another company's product?

Mr. CAFFERTY: I am going to object to the form of that question, your Honor. I think we should have a definition of what "proprietary" means.

[3702] Mr. Jacobson: Data supplied to you by a company generated by that company.

A. Let me say that my position was somewhat of an outgrowth of the studies that we had made—that is, the task force—and when I took the position as Director, it was my policy to make sure that no proprietary or let's say any information submitted by any applicant or registrant that was considered to be confidential would be maintained as confidential.

Q. And with respect to the registration-

The COURT: Did you say it was your policy it would be, or it would not be?

The WITNESS: It would be maintained as confidential.

By Mr. JACOBSON:

Q. With particular regard to the registration of another company's product, what was your policy with respect to the use of the company's confidential data in support of another company's application?

A. The staff was required to ask in all instances for information when the application was submitted. They were not permitted to use any data that was submitted by any other registrant for registration purposes.

Q. And would this be in all cases, or just in instances where consent had not been obtained?

A. All cases.

[3703] Q. Dr. Hays, the question I just asked you I'm not sure I made completely clear, so let me ask it again. You testified that your policy was to maintain or not allow the use of one company's data in support of another's application.

A. That is correct.

Q. My question to you was if the first company gave consent to the division to allow the use of another company's application, would that be acceptable?

A. That was permissible.

Q. And we have had some testimony in the case that the division granted applications for registration by a second company on the basis of another company's data. If that did occur, was it done without your knowledge or consent and was it contrary to your policy?

A. It was done without my knowledge and consent and contrary to policy.

[3704] Q. \* \* \* Now, your were up right at the top of the chart. You were the actual Director of the whole Registration Program, including [3705] enforcement, the whole Pesticide Program, including enforcement and registrations; is that right?

A. That is correct.

Q. Who was it when you were Director who was in charge of the Registration Program?

A. Mr. Alfred.

Q. That is Harold Alfred?

A. Harold Alfred was the Assistant Director for Registration.

Q. So he was the one who was in charge actually of that particular Registration Branch?

A. That is correct.

[3706] Q. And you had oversight responsibility over Mr. Alfred and also whoever it was that was in charge of the Enforcement?

- A. That is correct.
- Q. Now, Mr. Alfred wasn't the one who actually handled the registration when the came in, was he?
  - A. No. They were first reviewed by other people.
- Q. Sure. That was done by people down in the Registration Branch?
  - A. That is right.
- Q. And basically it was the program specialists who were responsible for shepherding the application through the process?
  - A. That is correct.

[3707] Q. Now, you testified about the policies that you implemented as Director of the Registration or Director of the Pesticide Programs. Were any of these policies regarding what Mr. Jacobson terms the use of data to support someone else's registration written down in the form of regulations or policy statements?

A. Not that I know of any specific details of policy.

#### Defendant's Exhibit KKK

[Testimony from *Mobay Chemical Corp.* v. Costle, W. D. Pa. C.A. No. 79-591]

[5] HAROLD ALFORD called as a witness by and on behalf of the defendants, being first duly sworn, testified as follows:

[By Counsel for Defendant, Mr. CAFFERTY:]

- [8] Q. What was your position immediately prior to 1972?
  - A. I was Director of the Pesticides Regulation Division.
  - Q. How long did you hold that position?
- A. From April of 1971 through into November of 1972; a little over a year and a half.
- Q. And what were your responsibilities when you were in that position?
- A. I was responsible for the administration of all the division functions which included the administration of the Federal Insecticide, Rodenticide and Fungicide Act except for the enforcement segment, the enforcement actions under the law.
- Q. Was one of your responsibilities then between 1972 and 1972 to oversee the functioning of the registration program?
  - A. Yes, sir.
- Q. All right. Now, prior to April of 1971, were you also employed by EPA?
  - A. Yes, sir.
  - Q. And what was your position at that time?
- [9] A. I was Assistant Director for Registration of the Pesticides Regulation Division.
  - Q. And how long did you hold that position?
  - A. From December of 1966 until April of 1971.
- Q. In December 1970 the pesticide registration functions were transferred from the United States Department of Agriculture to the Environmental Protection Agency. Were you the Assistant Director in charge of pes-

ticide registration both at USDA and after its transfer to EPA?

- A. Yes, sir.
- Q. So essentially, you were in the same position from 1966 to 1971?
  - A. Yes, sir.
- Q. What were your responsibilities as the assistant director in charge of registration?
- A. I was responsible for developing operating procedures and policies regarding the registration of pesticides and for overseeing the movement of paper work and the registration process.
- Q. Prior to 1966 were you also employed by the United States Department of Agriculture?
- A. Yes, sir. I was Assistant to the Director on the staff of the Division Director from 1961 through 1966.
- Q. And what were your responsibilities in that position?
- A. I had a wide range of staff responsibilities supporting the administration of the division, development [10] of regulations as far as pesticide registration is concerned, development of certain procedures and I edited and published the USDA Summary of Registered Pesticide Uses.
- [15] Q. I direct your attention then to 1967 to 1970 when U.S. Department of Agriculture processed pesticide registrations and issued pesticide registrations and let me pose the hypothetical question again. Assume an applicant came in and wanted to register a pesticide product with a brand new active ingredient, one that had not previously registered, what general types of information would the United States Department of Agriculture require that pesticide applicant to submit in support of his application?
- A. Well, first he would be required to submit extensive chemistry information on the ingredient and the product. He would be required to submit test data that would enable us to determine safety when the product is used as

directed, determine that the product would be effective and safe to use as directed, and that the directed use would not leave illegal residues on food or feed crops.

Q. So those are the three basic types of questions that you wanted answered by the data submitted by the first applicant?

A. Yes, sir.

Q. Now, suppose a second applicant comes in or came in between 1967 and 1970 and asked for registration for a [16] product that was the same as one that had previously been registered. What type of data did the United States Department of Agriculture require that applicant to submit?

A. If we already had the data on the previous one, the same questions of course would apply as far as effectiveness, safety and residues. If we already had the information to show safety and effectiveness and the absence of illegal residues, we wouldn't require the same data over.

Q. So the second applicant then would not have been required to submit additional data if none was needed?

A. If the original data applied, that's true.

Q. Is the system that you just described the system of registration based on established use patterns commonly referred to as based on established use patterns?

A. Yes, sir.

[19] Q. Did the United States Department of Agriculture as a matter of policy require the applicant to get permission from the data submitter to rely on the data that had been submitted?

A. We did require the submission of a complete statement or formula or authorization to refer to the original submitter's file for formula information, but not for test data. Q. Now you said you did require permission for the confidential statement of formula. Was that policy written down anywhere?

A. Yes, sir. It was.

### Defendant's Exhibit VVV

[Deposition of Nicholas Lee Reding, taken on behalf of the defendant.]

#### DIRECT EXAMINATION

Questions by Mr. CAFFERTY:

[28] Q. What about the patentability of a chemical, is that an important consideration?

A. Absolutely.

Q. If a chemcial was not patentable, if your patent lawyers said. "Look, we can't get a patent on this chemical," would Monsanto continue to develop that chemical as a pesticide.

A. That would certainly influence our thinking and, of course, it partly comes to the issue at hand. We're in a highly proprietary business and particularly with our unique approach to Europe. A proprietary position is absolutely imperative to use and it's conceivable that if we could not get [29] a patent but we thought that we could protect our innovation by virtue of the data we develop as part of that innovation that we might still make that decision to proceed but without some kind of protection it would be certainly less likely.

Q. And generally patent protection is something that you try to get in every case, would that be fair to say?

A. Yes, and data protection.

[30] Q. Okay. Now, when Monsanto attains a patent, does it just attain a patent in the United States of does it file for patents in other countries as well?

A. We file worldwide as we deem appropriate.

Q. What would be the factors that would influence whether you deemed it appropriate or not?

A. Well, there are a number of countries around the world where you can't get patents today or where there are some questions about the patent system and we would obviously take that into consideration but our general approach would be to file for patents wherever we think it gives us some degree of protection.

[31] Q. You said there is a number of countries in which the patent system is not very good. What is the basis for your statement?

A. Well, and you have to deal with it in degrees. There are countries where there is no patent system. The People's Republic of China is a case in point where you can't get patents today. Indonesia is another case in point. There are countries where you can only get a process patent which does not provide much protection since there are typically a number of processes that can be used to make any given compound. India is a case in point.

There are areas where there is question about the likelihood of getting a strong patent for ag-chemicals. The Andean block is a case in point where, in effect, a number of years ago they stopped given pharmaceutical patents and they attempted to look at ag-chemicals in the same way. Also countries where the patent system has not been tested by any jurisprudence at this point so until it is, there is some question about the validity of it. Brazil is a case in point.

So all in all, if you look at Eastern Europe where there are some difficulties, you look at Spain where you can only get process patents, and as I mentioned, the Andean block, Mexico, a number of years ago adopted what they call a certificate of invention which really gives you very [32] little protection. I mentioned Indonesia and India. There are in varying degrees a number of situations where the patent situation either doesn't exist or it's considered to be somewhat weak.

Q. In these countries which you mentioned, and you mentioned a number of countries, what has been Monsanto's experience with respect to the competition which it has faced from other companies selling the same pesticide as yours?

A. I can give you some specific examples. There are a number of countries that make great things of doing these sort of procedures. The Taiwanese are a good case in point and for years it was very difficult to get any kind of meaningful patent coverage in Taiwan and as a result, if you look at a number of major proprietary products in this agricultural chemical area, in some cases there are multiple producers in Taiwan.

Another case in point is in the Eastern block. Hungary, specifically Hungary went through a period where they would reward the inventions of the Hungarian country but not the non-Hungarian countries and, in effect, they are discriminating against non-Hungarian countries and as a result, there are a number of Hungarian countries that have made products that were the inventions of non-Hungarian countries and multinationals.

[33] A third case in point is Israel. In Israel there is a procedure for opposing patent applications and in some cases the Israeli countries have been successful in their opposition by virtue of the local procedures and so there are a number of Israeli companies that are making a lot of these products.

And it's not only a matter of Monsanto not being able to get patents in their country but then we are exposed to other countries where the patent situation is not strong, and in most cases by virtue of the way they give patents as a product comes off patent, assuming there is no other protection of that product, they will automatically make it if the market of suitable proportions exists.

Q. I just asked you a question about the problems that might occur because of the absence or the insufficiency of patent protection and you gave me your opinions as to what some of the problems might be. What I would like to know is what specific problems has Monsanto encountered in the agricultural chemicals market, pesticide market, as a result of what Monsanto feels is insufficient foreign patent protection?

- A. Well, of the three specific cases that I have mentioned, the Hungarians have made one of our proprietary inventions.
  - Q. Which invention is that?
- [34] A. Roundup, which is perhaps the newest and one of the more exciting inventions in the ag-chemical field. The Taiwanese have made two of our products, one being Lasso, which is a herbicide for corn and soybeans and the other beans, and Machete which is a rice herbicide. And in the case of Israel, an Israeli company is making Lasso even though we still have pending a patent application which is going through the prolonged opposition procedures. Actually in the case of Hungary, there are two companies making Roundup. In the case of Taiwan, at one time there were, I believe, four or five companies making Lasso and Machete.
- Q. And all of these chemicals, Roundup, Lasso, and Machete, were all patented in the United States at the time?
  - A. Yes.
- Q. Now, the companies in Hungary that were manufacturing Roundup, were they selling that Roundup in competition with Monsanto in other countries?

A. Yes.

[41] Q. Okay. I have got a list—off the track here. I wanted to ask you that a little later but we got to it ahead of time.

Okay. I think we were up to the factor of patentability and proprietary protection as one of the factors which you consider regarding development. Are there any other factors other than patentability and the others that we discussed already which you would consider in developing an agricultural chemical?

A. We talked about the uniqueness of the invention in terms of its application to solve a problem that has not been solved from Monsanto's standpoint. We talked about patents and I mentioned the data protection. Those would be primary issues.

Obviously we would look at what is the likelihood of success, do we have a lead that indicates to us that we can arrive at an invention and obviously as we get further along in the invention process, we will think about the environmental characteristics and work that over very carefully to make sure that this is going to be a compound that is acceptable in the environment that can meet pollution control standards and things of that sort and that there is no adverse effect, per se, that the toxicology is [42] proper, residue, metabolism, and environmental fate.

Q. Are those the major factors, then?

A. I would say so.

[57] Q. How many years now has it been that the Agricultural Chemicals Company has been the major source of operating income for Monsanto?

[58] A. I would say that it's been since the mid-seventies early to mid-seventies.

Q. And what are the projections for the Agricultural Chemicals Company to remain as the leading contributor, shall we say, to the operating income?

A. Well, we're investing a lot of money in research and so we obviously think that research should pay off so we think that the Ag-Products Company should continue to grow if we can continue to develop the technology that is appropriate.

Q. Okay. Do you know when Roundup was patented, the active ingredient in Roundup?

A. I'm thinking. I believe that it was 1974.

Q. Okay. How about Lasso, do you know when that was patented?

A. I'll tell you approximately. Okay? I think that it was in approximately 1969, 1970.

Q. Now, those two of the three—let's get back to your affidavit. You said in your affidavit later on in paragraph three that of the ten major herbicides developed by industry over the last thirty years Monsanto, has developed

three of them. Which would be the three that you would characterize as three of the major herbicides?

- A. Avadex, Lasso, and Roundup.
- Q. Do you know when Avadex was patented?
- [59] A. Again, I'm going to tell you approximately. I think that it was about 1967.
- Q. Okay. So then Avadex, Roundup, and Lasso were still under patent, is that right?
  - A. Yes, in the United States.
  - Q. Do you know when they expire in the United States?
  - A. Yes.
  - Q. Okay. When will Avadex expire, approximately?
- A. Let me see. First of all, not to over do this with you, there are different kinds of patents, as you know. There is a compound per se patent on the chemical itself, there are composition patents that involve the compound plus adjuvants, there are process patents, and there are use patents. So when you talk about patent expiration, you know, these patents generally expire in different times but——
- Q. Generally do you have each of these types of patents on Avadex, Roundup, and Lasso?
  - A. It varies from product to product.
  - Q. Do you have for each product a compound patent?
- A. We have a compound patent on Avadex and on Lasso. We have a compound patent pending on Roundup but we have use process—use and process patents.
  - Q. On each, on all three of them?
  - A. Yes.
- [60] Q. What about on the active ingredient itself? The compound, I would assume, would be the chemical itself or would it be the chemical in its formulated use and process?
  - A. No, it's the chemical itself.
  - Q. And that's still pending for Roundup?
  - A. Yes.
- Q. All right. Well, then, when would the Avadex patents expire, roughly?

- A. Roughly 1984.
- Q. And what about the Lasso patents?
- A. 1986, '87.
- Q. And what about the Roundup patents?
- A. 1991.
- Q. Now, it also says in your affidavit in the second sentence in paragraph three that this enormous increase in sales and operating income has been almost entirely attributable to the continual development by Monsanto of new agricultural herbicides. Does that mean that basically the principal operating income which you derived from Monsanto from your Agricultural Products Company in 1980 came from the sale of herbicides?
  - A. Yes.
- Q. Approximately how much of it comes from the sale of herbicides as opposed to the other things that you sell?
  - A. I would say ninety percent, approximately.
- [73] Q. How will that, this 3(C)(1)(D) data consideration or data use, have a substantial impact on Monsanto's sales and profits and a chilling effect on Monsanto's incentive to research and develop new products?
- A. Well, it goes back to what I call the proprietary nature of the products. We spend a lot of money in inventing these products and, as you know, it's a very high risk research. For every ten thousand compounds that our industry typically synthesizes, they commercialize one, assuming that EPA is registering products at all, which wasn't the case for a while as you know back in the seventies, and we may typically have twenty to twenty-five million dollars invested in that product before we ever build a plant just to go through the registration procedures, the original research and registration procedures, so it's a very high risk and as I pointed out, of some ten herbicides, we have been fortunate enough to have three of them and I think very clearly while patent protection is one issue, the issue of data protection is also of great importance and if we felt that we could not pro-

tect our data either in terms of [74] it's exclusive use or in terms or data exposure, that would be a very serious deterrent in terms of our wanting to take the same risks. Another facet of that is that, as I mentioned, there are countries in the world where you can't get patents or where the patent system is weak.

Q. I want to limit it to the United States now and data use in the United States. We will get to the second part, the Foreign Countries, in a moment. I'm sorry to interrupt you.

Is there any other way in which you think data consideration or data use would have a substantial impact on Monsanto's sales and profits and a chilling effect on Monsanto's incentive to research and develop new products?

- A. You like those terms.
- Q. Yes, they're yours. I think I will use them.

A. Yes. If you look at the patentability of products, very often as people synthesize new chemicals, they file product patents that generically cover a number of compounds and it is not at all unusual or unlikely that there may be compounds within that filing that have not precisely been identified as having been superior activity or utility until later in the patent life. And that being the case—or let me give you the second case and then give you the conclusion as I would look at it.

There are also cases where perhaps a person cannot get [75] a patent on something because of obviousness, someone else has a patent and the Patent Office determines that the patent was obvious and you don't get protection in either of those cases and there are a number of those I think that without data protection either in terms of exclusive use or limitations on the data exposure, I think there would be a real question as to whether a company would proceed toward the commercialization of products in that kind of situation.

Q. Okay.

A. Because invariably they are going to have to spend this twenty to twenty-five million dollars before they build a plant and I just think that they would look at it and say that that investment is questionable.

# TRIAL TRANSCRIPT

[41] Dr. Will D. Carpenter, was called as a witness, and being first duly sworn to tell the truth, the whole truth and nothing but the truth, testified as follows:

#### DIRECT EXAMINATION

By Mr. HEINEMAN:

- Q. Would you state your name for the court, please?
- A. Will Carpenter.
- Q. And where do you live, Mr. Carpenter?
- A. I live in Ballwin, Missouri.
- Q. And could you tell us by whom you are employed?
- A. I'm employed by Monsanto.
- Q. And in what capacity are you employed?
- A. I am director of environmental management.
- Q. And when did you assume that position, Dr. Carpenter?
  - A. In November of 1980.
- Q. And prior to that date, sir, in what capacity were you employed by Monsanto Company?
- A. Prior to that date, from 1977 until that date, I was director of environmental operations for the Monsanto Agricultural Products Company.
- Q. Now I'm going to get into a little more detail concerning your background, but I'd like you to tell us, a [42] little bit, if you would, about the Monsanto Company. Now can you tell us what is the business of Monsanto Company?
- A. Well, basically, Monsanto is in the business of primarily making synthetic fibers and chemicals. We are divided into five operating companies that operate more or less independently: The agricultural company, which I've just mentioned and of which I was a part; the textiles company; the industrial chemicals company, and that covers a whole range of products including aspirin and

plasticizers and flavors and medicines, and what have you; the chemical intermediates company which do just that, provide chemicals that are used primarily to make other finished chemicals; and finally the plastics company which makes plastics; and the various supporting staff units for that.

Q. Okay. Sir, if you would please examine—and let me hand you for your examination what's been marked as plaintiff's exhibit number 1. And I'd ask you to examine that and identify it for us, please?

A. It is a brief summary of the activities of Monsanto, their sales by product, what some of their goals are, where their plants are located, how their organization is made up, how many people work for it, a little bit about the product in each one of those five operating companies.

Q. Does it in general terms talk about where locations of facilities are located?

[43] A. Yes.

Q. Where does Monsanto Company operate, sir?

A. Well, it operates on a worldwide basis, in either sales office or manufacturing, probably in over eighty countries. I don't know whether the specific number is listed there, but it's a broad-based company.

Q. Now let me deal, if I may directly, with the Monsanto Ag Product Company, one of the five operating companies of Monsanto. And you say were a part of that company; for how long, sir?

A. From the time of its formation in 1960 until the time I left in 1980.

Q. (By Mr. Heineman) Very much so, Judge. Approximately how many employees does the Ag Products Company have, [44] sir.

A. I believe we have around six or seven thousand, in that range.

Q. As opposed to how many employees in the entire company?

- A. I think the entire company, in 1980, had about forty thousand, forty-five thousand in the U.S., and about seventeen thousand internationally.
- Q. And insofar as the sales of the entire Monsanto Company are concerned, do you know approximately what percentage of those sales are accounted for by the Monsanto Agricultural Products Company?
  - A. Around sixteen percent.
- Q. And insofar as the operating income of the profitable units of Monsanto Company, how much of that operating income approximately is accounted for by the operations of Monsanto Agricultural Products Company?
- A. I think it's around seventy to eighty percent; a substantial amount of it.
- Q. And to what is that substantial percentage of the operating income of Monsanto Company attributable?
- A. That is due to the sales and the profits thereof, primarily, of our herbicides.
- Q. And which herbicides do you have specific reference to?
- [45] A. The two most important ones are Roundup and another product called Lasso, and then there is several others including Avadex BW, Avadex, Ramrod, Randox. And those are the principal ones.
- Mr. Heineman: If the court please, as we go along I have extra copies of these exhibits that he identifies for the court to examine as we go. And copies have been provided to the attorneys for the Government.

The Court: All right.

By Mr. HEINEMAN:

- Q. Dr. Carpenter, let me hand you what has been marked for identification purposes as plaintiff's exhibit number 3, and ask you to examine that and tell the court what it is, please?
- A. This is an organizational chart of the technical efforts of the Monsanto Agricultural Products Company, which consists primarily of the development department and of the research department. It gives the various slots,

the titles, and the name of the person that is currently occupying that position.

Q. And I note that pages 1 and 2 relate to the product development group. Could you tell us—now these are all employees of the Monsanto Agricultural Products Company; is that correct?

A. That is correct.

Q. And would you tell us what is the function, generally, of the product development group?

[46] A. Well, after our research department has identified a potential candidate for commercialization; in other words, this looks promising-after a year or two of testing, the product development department then works with the various universities and experiment stations around the country, around the world, in putting out experiments, testing with farmers to see if the product can be used safely. They then further take that test data, and that data is used to submit to the EPA and the other appropriate agencies for their inspection and determination as to the validity of our claims for the product. Then they further, once we have obtained that registration, then these technical people take that expertise and see that our marketing people properly know how to use it, and the customers, and they hold farmer meetings on the proper use of it. So they both generate the data and then they see to it that it's used properly.

Q. Now I note that on page three of exhibit number three, could you tell us in very general terms what that page demonstrates?

A. Well, this is the general overview of the research department. And this gives you in broad terms the various types of research that goes on in the research department. For instance, we have one man that is involved in the various chemicals, another one involved in biological research. The one, moving over to the right hand, is involved in [47] environmental science. And then finally we have one that coordinates our international research.

And this then briefly tells the people that are managing our agricultural research.

- Q. Now this research division is only with respect to the Ag products company; is that correct?
  - A. That's correct.
- Q. This isn't—has nothing to do with all the rest of the research department that is out there at Monsanto?
  - A. Independent of anything else.
- Q. Now, if you go to the next page it shows biological research. Now could you tell the court generally what is involved for Monsanto Company in terms of the biological research, in general terms?
- A. Well first, we must identify what is an appropriate target for us to go look for. And let's say we are looking for Johnson grass. The chemists will synthesize a chemical and say we think you ought to try this to see if it will kill Johnson grass. The biological group will then devise means of testing that chemical against Johnson grass so that we can very quickly determine if there is activity. For those compounds that look promising we carry out much more involved detailed tests that will ultimately—in each case we're trying to make a decision as to whether to continue with the product or drop it.
- [48] And in the biological group primarily they are broken up into two main groups, herbicides or weed killers, and then more sophisticated newer type compounds called plant growth regulators that will cause the plant to do something you want it to do. For instance, one of them we have when applied to sugar cane will cause us to get as much as a ton of sugar more per acre off of sugar cane. It fools the sugar plant into producing more sugar, if you will. So this is the biological group.
- Q. Now these plant growth regulators of course are governed by and regulated by the environmental protection agency?
- A. The same laws, same regulations that govern pesticides.

- Q. And their safety has to be determined by that agency just as you would a weed killer.
  - A. Exactly the same.
- Q. Now if you turned to environmental science, sir, which is on the next page. I note that is under Dr. Sharp. Could you tell us what—generally what that department does?
- A. As a compound shows promise for commercialization, among those things we must find out as soon as possible and continuing through its commercialization, its impact on the environment. Now in order to do this we must determine what happens to it in the soil, what happens to it in the water, [49] what happens to it in animals, what happens to it in crops. We need to know how much is there, in what form is it. And all these are studied. In addition to that, what happens if quail are sprayed, what happens if rabbits are sprayed, the impact on wildlife, on fish and in lakes, and so forth. So this group carries out those studies that determine the impact of the chemical on the environment.
- Q. And those results—those studies again comprise data which is submitted to the Environmental Protection Agency?
  - A. Yes, it does.
- Q. Now the next page shows the organization of the synthesis department with Dr. Rueppel in charge. Could you tell us what that group does in general terms?
- A. Well, these are the people that synthesize or make, invent, discover new chemicals. By and large we find that these people, in order for us to get up to what we call critical mass, get enough there that we've got some odds at discovering, we need to invent, discover somewhere between five and ten thousand new chemicals a year, because we're only commercializing about one out of ten to one out of twenty thousand chemicals.
- Q. Excuse me, when you say one out of ten you mean one out of ten thousand?

A. One out of ten thousand to one out of twenty [50] thousand chemicals eventually reach commercialization. so that these people are charged with several things. First of all they must be smart enough to figure out what are new techniques of making chemicals, and then what can be done with old areas of chemistry to modify them so that you then have new chemistry.

So just the making of chemicals is not as important as figuring out how to go make something—a completely new class of chemicals, and developing new techniques for making them. And this is a part of the synthesis group.

Q. All right. Now I will get into more detail on that synthesis effort later on. But I just want to have a general flavor of what these various groups do.

Next we show chemical research. What do they do? Does that differ from the synthesis group?

A. Once we have made a chemical and decided that it is indeed worthy of commercialization, then we must have people that must go do several things. One is how to make it in a million pound plant as opposed to a few grams in a test tube. And that's the process group. Then in addition, having made the chemical we must put it in a form that the farmers can use effectively. The chemical as it is, by and large, could not be used by the farmers, but must be put in such a way that the farmer can put it in his fertilizer solution or in his water, or mix it with his seed or [51] whatever, and do it effectively and safely. And that is the formulation group.

Q. And that's on the next page we see process/formulation technology?

A. And that is merely an expansion showing the detail of what—of the two things I have just described.

Q. And these are the people that actually do that work?

A. That's correct.

Q. Now where are these people located? You mentioned some—you mentioned something about an international department. Where are the people located?

A. Well, a great number of them are at research labs here in St. Louis. But in addition, we have research facilities in Brazil, in Europe, in Latin America; in Asia we conduct—also conduct research and development. So in a word we have been worldwide.

Q. Now I note on page nine we have plant sciences. Can you tell us what that group accomplishes?

A. Well, in addition to looking for the conventional chemicals that will control an insect, control a weed, control a fungus, we have substantial commitment to looking at new ways of controlling insects and diseases rather than just using chemicals. For instance, we found that we can actually cause the plants to make their own antibodies, [52] if you will, to make it the pop expression, whereby the plant will secrete the chemicals that will kill the pest rather than having to use a chemical to do it. In other words, we make a plant resistant to an insect or to a fungus, or we could spray it so that the weeds don't bother it. And this is what things like the disease insect control group, host/patogen group, and the cell biology group are doing. They're actually maybe even trying to invent new plants by isolating special cells of the plants and culturing new plants that will be resistant to herbicides. For instance, you could spray them over the top without having to worry about crop damage. So this is the far out group. This is the group that are looking for things that will be our product after the year two thousand.

Q. When you say develop a plant that would be resistant to herbicides so that you could spray right over the grown plants, would you develop that a little bit? What are you talking about there?

A. Well, no herbicide is perfect. We'd like to think that we've come close a few times. But no herbicide is perfect, there's always a way to damage a crop plant, damage your soy bean crop if you put on too much, or damage the corn plant if you get it in the wrong place. Well, if we could treat the corn plant so that no matter how much of

the herbicide you got in the wrong place, or sprayed at the wrong time, [53] it would not damage the corn plant at all whether you sprayed it when you planted it or sprayed it over the top. The corn plant would then become resistant, so that then you could get the weeds any way you wanted to.

Q. What benefit would that have to the farmer and to yields?

A. Well first of all, it would give him access to a wider range of herbicides that he doesn't have a choice of. It would take off the impact of just about the time he gets ready to spread his herbicide it rains and he can't get back in the field for two weeks. And by then either the crop is at a stage where it will be damaged, or the weeds are too big to be killed. Well, if you have one—

The COURT: Off the record. (Discussion off the record.)

The COURT: Go ahead.

A. But at any rate, this is getting into materials—all of these techniques, I imagine, would be a substantial improvement in the environment. You're then dealing with products that are not biocides, but chemicals that stimulate certain parts of life. So that you would get an improved impact on the environment that way.

By Mr. Heineman:

Q. All right. Next I'd like to have you identify what's been marked for identification [54] purposes as plaintiff's exhibit number 2. I have a more manageable version for the court.

Now Dr. Carpenter, if you would please tell us what plaintiff's exhibit number 2 is.

A. This is a map showing the location of all the various facilities of the agricultural products company's operations. The red dots being our marketing and our development groups and the triangles being—

Q. Which are blue?

A. Blue—our research facilities. And our manufacturing locations being square black, I believe, or green; green perhaps. We keep our marketing and our development and our technical people together so that we see that our technology is used properly. Our manufacturing facilities are, for the most part, concentrated in the U.S. But we still have manufacturing facilities in a large number of countries: Canada, Brazil, Argentina, Europe, Australia, Korea. And they're quite widespread, and by and large, in the key agriculture countries of the world.

Q. Now you mentioned, sir, something about keeping facilities together in certain locations. Could you elaborate on that a little bit?

A. Well, if we identify a new agricultural opportunity, let's say in South Africa where they grow a lot of corn, when we go down there and test this, by and large we're [55] doing two things at once. We're trying to establish a marketing system, what distributors do we use down there, how does the farmer buy his material, or how does he pay for it, how his material is warehoused. But at the same time we have a rather extensive technical program too, and those two programs have to go together not only initially but down the road. A product that works well on corn in Missouri may or may not work well in South Africa. And you have to carry out the same type of intensive testing in South Africa that you do in Missouri. Or if it's wheat, you carry out a very intensive program in Australia just like you would in North Dakota. So that we keep our technical and our marketing people together so that the technology is transferred correctly.

Q. Now you also mentioned something about test farms. Would you tell the Court generally what you mean by that expression.

A. Well, we have farms just as the University of Missouri or Illinois has, where they have their experiment station farms. We have them also whereby we can control experiments over several years that we want to follow the fate of a chemical in the soil, where it can be on our own land and under our control, where we can carry out very elaborate experiments. And this farm is set up to

conduct very sophisticated experimental procedures very similar [56] to that done at the agricultural experiment stations that are a completely different type, nature than done there.

Q. In what respect is it different?

A. Well, the agricultural experiment station is usually set up to solve a problem for the farmers in Missouri. Usually this is limited to the study of new varieties or control of certain pests, or crop safety. Ours are to test a wide range of chemicals, probably on a given crop, that may or may not be a major problem. For instance, we will test all crops at our farm here in Missouri on crops that are—weeds that are important in Belgium because we want to get as much information as soon as possible. We'll test it on weeds that are problems in Canada, like quack grass. Quack grass in Canada is as big a problem as Johnson grass is in Missouri. We will also carry out various types of experimental design equipment, like means of controlling photosynthesis whereas you have the same types of scientists, their skills and experience and types of experiments would be different than those at the University of Missouri or in Illinois.

Q. Dr. Carpenter, I wanted to get you started initially talking about the company itself, and would like at this time to have you tell the Court something about your personal background. I know that you received a bachelors degree from Missisippi State. Can you tell the Court in [57] what year?

A. I received my bachelors in 1952 in agronomy, soil chemistry.

Q. And for the benefit of the record, sir, would you tell us generally what agronomy is?

A. Agronomy is the study of crops—usually, most ecologists—crops and soils, and specifically what we call field crops such as cotton, corn, soy beans, rice, as opposed to horticulture crops, which would be your various fruits and vegetables.

Q. And after graduation from Mississippi State what did you do then?

A. Worked briefly at an experiment station in Mississippi. Then I went into the service and was in the artillery in the U.S. and Korea, and was there until mid to late 54, 1954.

Q. And what did you do then, sir?

A. I then went to graduate school, to Purdue, got a masters in 56 and a Ph. D in 58 in plant physiology.

Q. All right. Now would you tell, for the record, what plant physiology is, basically?

A. Plant physiology is—represents a study of the functions of the plant, how does it make certain things happen, how does it get its energy to build new cells, how does it trap the light from the sun for photosynthesis, how does [58] it transport things from one part of the plant to another, this type of thing, functions within a plant.

Q. Then in 1958 you joined Monsanto Company?

A. That's correct.

Q. In what capacity, sir?

A. I joined as a research chemist in plant and animal nutrition studies. And then went to some rather basic biochemical studies, synthesizing radioactive materials for studies on cell wall synthesis. And then in 1961 joined the Development Department of the Agricultural Company.

Q. And what generally did you do in the Development Department?

A. Well, we worked very closely with the universities and experiment stations. At that point in time I was working in the southeast quandrant of the U.S. I had about twenty States ranging from North Carolina across through to Missouri, Arkansas, and Texas. And we would work with the various scientists at the university. If they would have an objective of solving a problem say in Missouri, I would have a chemical that I thought was a condidate to solve that problem—now I wanted to solve it in Missouri and North Carolina both, they didn't really care

whether the solution came from Monsanto or Dupont or whoever. But both of us were interested in trying to control that patricular pest, so to that extent our objectives overlapped for a fair amount, [59] and so I would conduct my own test, put out my own experiments and visit with experiment stations, review their results and look at their tests, and then relate this back to what we should be doing with our product.

Q. And you served in that capacity for four years, until 1965, when you became manager of herbicide development; is that correct?

A. That's correct.

Q. And did you then continue generally in the same type of functions?

A. Yes, except at that point in time my responsibility became worldwide, and I spent a great deal of time traveling to a number of other countries seeing to it that we were then doing what I had been doing in the U.S., that we were setting up procedures and hiring people to look at agricultural problems on a worldwide basis in a manner that we had been doing it in the U.S.

Q. And you did that until 1968. And what—how did your functions change then, sir?

A. Well, I then became director and we then enlarged our operations considerably both U.S. and—domestic, and put a number of scientists across the country carrying out, with our own forms and so forth, these experiments on a much more intensive scale.

Q. And then in 1977 I think you previously testified [60] you became Director of Environmental Operations for the Agricultural Products Company?

A. That's correct.

Q. Now in these capacities with Monsanto Agricultural Products Company over the years have you had any connection with the registration functions?

A. Yes.

Q. Would you please tell the Court?

A. Well, in the early days, in 1961, the registration functions was a matter of the Development Department. And a number of us prepared a petition to submit to U.S.D.A. at that time. In 1968 the registration functions as such moved over to research, and organizational change, but we still generated the use data and did the residue studies on locations that were a part of our registration procedure and were submitted. And that arrangement stayed until 1978 whereby we participated in writing the label, drafting the proposed label to be submitted to EPA, plus the efficacy data on how effective it was. crop safety and the residue locations. Then in 1978 after I had become Director of Environmental Operations, the registration group was transferred over to me and reported to me. So that the registration group, those that prepared all of the data, pulled it together, our Washington representatives and so forth, were a part of my group.

[61] Q. Now during the time that you were in the product development functions, was that the time when lasso and roundup were discovered?

A. Yes.

Q. And then were you then responsible for the develoment effort on those two products?

A. Yes, I was.

Q. Now in these various functions that you have served in the Agricultural Products Company, have you had occasion to become familiar with the cost and investment in research and development by the Ag Products Company?

A. Yes, yes. This has been a part of my responsibilities since 1961.

Q. And what connection, if any, have you had in those capacities with patent applications and product registrations and the data submitted for each?

A. Considerable. Patent applications are usually a direct relationship between the synthesis chemist and sometimes the biologist and the patent attorney. But the value of the impact those patents have, determine to a large extent what chemicals we test. So that the relation-

ship between development, the patent attorney who's handling our patents, and the Research Department is kind of a three-legged stool. And the interchange between the three must go on at all times. The data as opposed to patent data, [62] which is a very narrow small segment of the data that is used for registrations, is probably a couple of orders magnitude greater in complexity, amount, time to get it and so forth. And there we work towards—I worked and had responsibility for seeing that the registration data was given.

Q. All right, sir. I'd like to hand you what has been marked for identification purposes as plaintiff's Exhibit number 8, and ask that you examine that and identify it for us, please.

A. This is a biographical sketch of my activities primarily since I've joined Monsanto.

Q. And I note in connection with that exhibit there is some discussion of some trade and professional societies. Would you tell us what these regional weed science societies are that you belong to?

A. Okay. The North Central Weeds Control Conference comprises the professionals from Michigan and Ohio and Kentucky across through the Plain States, Nebraska, Kansas, North and South Dakota and Oklahoma. It's a professional society of something less than a thousand members from the universities, from the Government, and from industry. And their common bonds are those scientific aspects of weed control. I served as president of that in the mid-70's.

Then we have a national organization that is independent of the regional ones which comprise the professional [63] scientists of both Canada and the U.S.—and I was president of that organization in 1980—of about two thousand to twenty five hundred members.

Mr. Heineman: Now, your Honor, we would offer, Exhibits 1, 2, 3, and 8 at this time.

The Court: Is there objection?

Ms. MAYER: No objection.

The Court: It'll be received. Off the record.

By Mr. HEINEMAN:

Q. Now Dr. Carpenter in connection with the scope of FIFRA, can you define for us that a pesticide is?

A. Well, a pesticide is any substance-

Ms. MAYER: Your Honor, objection, as far as he's asking the witness to testify as to the legal definition of FIFRA.

The COURT: Well, overruled. Go ahead.

A. A pesticide is any substance that is used to control, kill, mitigate, reduce a pest. And pesticides include [64] the categories rodenticides, which is mentioned in the act itself; fungicides and insecticides. But it also includes herbicides and plant growth regulators, so it's a fairly broad category that comes under the definition of pesticides. Any time the substance claims are made for controlling pests, it comes under the purview of that.

By Mr. HEINEMAN:

Q. Of the act of FIFRA?

A. Yes.

Q. So that a plant that may be very desirable in one context and undesirable in another, would be a pest in the other context?

A. Yes. The example that always gets everybody's attention is a rose in a cornfield is a weed.

The COURT: Well, Johnson grass makes pretty good hay if you cut it before it heads up.

A. But if it's in your soybeans that's something else.

By Mr. HEINEMAN:

Q. All right. Let me get into a brief historical overview of pesticides and how they have been developed over the years. Before pesticides came along what did farmers do to control weeds?

A. Well, over the years as far as controlling weeds there were two things they did. They had human labor, which was the first thing. And that means pulling them out by hand or use of a hoe. And that still represents the single [65] biggest source of human labor in the world today, is taking weeds out of crops in most of the world. And then animal labor, which is nothing more than the mule and the double shovel, or running cultivators and so forth. And then ultimately mechanical energy, if you will, and that's the use of tractors and still just more sophisticated cultivation instruments. So human, animal, and mechanical labor was used to remove weeds.

- Q. Okay. Now prior to World War II, I, guess, is when the first pesticide came along in the herbicide arena; is that correct?
  - A. That 's correct.
  - Q. And could you tell the Court what those were?
- A. Well, just prior to World War II they had very simple inorganic compounds that you commented on earlier, such as sodium chlorates and even things like the arsenic compounds which were inorganic, and they were used. But they were non-selective. In other words, they would not allow plants—crop plants to grow either. It wasn't until after World War II that we got into the so-called organic selective herbicides.
- Q. Now in the early days of these herbicides were any of these materials proprietary?
- A. The first proprietary herbicide that was on the market, to my knowledge, was Dow came out with a product [66] about in 1950, thereabouts, called premerge. The products previous to that were primarily known as the phenoxy group which is the 2,4-D, 2,4,5-T group. And those were more or less came out of the Government screening during World War II. And those were not proprietary.
- Q. Was there a term that you would use to describe those compounds prior to the proprietary ones coming along?
- A. Well, in terms of the type of weeds they were used on, that would be one way. In terms of how they were located on the marketplace you could call them commodity chemicals, indicating that they were widely available from different sources like fertilizers or like seeds. You

could go buy soybean seeds from different people. You could buy fertilizers. Well, there were a large number of manufacturers of the phenoxy 2,4-D's and 2,4,5-T's.

- Q. Did Monsanto manufacture some of those products?
- A. 2,4-D and 2,4,5-T and some of the others.
- Q. And there were other companies as well that did the same thing?
- A. At one time there were up to ten to fifteen companies that manufactured those particular products.
  - Q. And those you say arose out of World War II?
- A. The phenoxies came out of World War II research, yes.
- Q. Now how do you differentiate that kind of a [67] chemical from what you called a proprietary chemical?
- A. Well, in my mind a proprietary chemical is one that comes out of a company's research program where it identifies a chemical where nobody has identified it before as being a herbicide, and conducts the research that leads to commercialization as a herbicide, and at least initially is the only supplier of that herbicide. It's their proprietary knowledge that led them to it. Whereas a commodity chemical comes out of some large public body of knowledge, commodity chemical does.
- Q. And what were the best known post-World War II commodity chemicals?
- A. Well, in the field of herbicides it was 2,4-D and 2,4,5-T by far. There were a number of insecticides that were used. I am more or less in the area of herbicides, and I'm not too familiar. But 2,4-D and 2,4,5-T were commonly regarded as proprietary. Parathion and methyl parathion which were used for insect control on cotton and other crops came out of World War II in a slightly different way in that they were identified in part through the German poison gas program during World War II. And there were several manufacturers from the beginning, of the parathions.
  - Q. Is DDT a chemical of that type?
  - A. DDT is another one, yes.

Q. Now was the efforts, as these chemicals developed, [68] to make them selective as opposed to wiping out the crop along with the weed.

A. Well, these compounds were the beginners of that, of a group of pesticides that could be applied selectively. In other words, they could be put on—the phenoxies could be put on corn without killing the corn. And they would kill the broad-leaf weeds. That was the definition of selective. And yes, the D's and T's were selective.

Q. Now I'd like to discuss somewhat with you, or have you describe to the Court, the correlation, if any there be, between the growth and U.S. agricultural product activities and the development and use of pesticides, and in particular, if you could discuss that in the herbicide arena, please?

A. All right. Well, if you start all the way back to when man started agriculture, probably the first thing he did was his own selection of seed rather than just depending on growing plants from the wild. So he selected and saved his seed and then learned to cultivate. And then he learned eventually to apply fertilizers. And then he eventually learned how to apply other components. He tried to control his pests. And the first thing he tried to control were the insects and the diseases. These were the most obvious. Being able to control weeds was about the last thing he was able to do other than by the use of labor. And [69] gradually as he got to where he could use herbicides he had brought in a number of minor scientific agriculture. So yields had already started to increase. So we had hybrid seeds and good fertilizers and we recognized how to take care of the land.

Then beginning at that point, in the late 40's, things that were really limiting production at that time, perhaps as much as anything, was the ability to control the weeds that competed for the plant nutrients, for the moisture, sunlight, and what have you. Soybeans is a particularly good example since they're grown in a large part of the country. You can pretty well plot the soybean yield per

acre, annual average yield per acre, starting in about the late 50's, early 60's until now. And there was a very close parallel with the better soybean herbicide that came out and the yield of soybeans. You just couldn't grow soybeans in certain parts of the South and the Midwest, and some of the heavy soil areas because of Johnson grass, crab grass, what have you. And many fields would be abandoned. And being able to get twenty bushels per acre or thirty bushels per acre rather than zero, just done wonders to the soybeans yields per acre.

Q. And what is the largest cash crop in the United States today?

A. The largest cash crop, depending upon price, is now somewhere between wheat and soybeans, displacing—[70] cotton use to be way up there. And now wheat, corn, soybeans are all extremely high, and the acreage has continued to increase.

Q. How many acres a year are planted in the United States in terms of soybeans and corn production?

A. Corn is now approaching between eighty and ninety million. Soybeans are now approaching between sixty and seventy. In the late 50's, early 60's, soybeans were less than half that and corn was actually about a little bit less than that. But the soybean acreage has almost doubled in the last thirty years.

Q. Does Monsanto anticipate any connection between the yield in terms of soybeans and corn production, and the use of plant growth regulators?

A. Yes. We think that the future of plant growth regulators, these materials that can modify the growth of plants, will do as much for agriculture as the use of pesticides have done in the last forty years. We think that they can represent the next big growth opportunity for increasing agriculture yields.

Q. Let me get a bit, if I may, into the subject of the research and development of a pesticide. Now can you tell us what all the considerations that—well first of all, let me step back a moment and say now in your capacity with the Monsanto Agricultural Products Company did you have any [71] participation in the decisions about the development of pesticides?

A. Yes.

Q. And was there a group that you participated in in which you made those decisions?

A. Yes. We used various terms for the management group, and the composition changed. The term that we're now using, and used from about 1973 on, was called the new product board. In the mid-1960's we used the term pesticide product board. And those terms have shifted. But yes, there is a management board. I was on the pesticide product board in the 60's, and then I joined the new product committee board in 1976.

Q. And in terms of the decisions and considerations that go into developing a pesticide, can you tell us what the problems are that you take into consideration?

A. Well first of all, the company has got to decide whether it really wants to get into the pesticide business. It's got so many dollars that it can afford to spend on research or development. And it's looking at a lot of competing places to spend that money. It can spend it to go find a better aspirin or to find a better plastic, or to find a better soap, or to find pesticides.

So when they name a commitment to get into the pesticide business they have got to make a commitment to get into [72] the business with no pay back. They better plan on no pay back for anywhere from ten to twenty years.

Now the thing that you have to take into consideration when you want to get into the pesticide business is this. First of all, I want to find something to be solved that's a big problem out there. It's got to be awfully big because if it's going to take you a long time to find the solution. When you find it, it better be a pretty big solution. Another thing is, it's got to be a very difficult problem to solve, as only those organizations that are willing to commit to a long-term effort and apply a lot of resources to it are going to be the ones that have a chance at solv-

ing the problem. So that there aren't going to be that many people out there trying to solve it in the first place.

And then finally, it's got to be a problem that will still be a problem twenty years from now, because it could take you that long to solve the problem. And if you look at it and say I'm going to solve that problem now, and it doesn't exist twenty years from now, then you've got a solution with no place to go.

And then finally, it's got to be a problem that you think you can find the solution, that you can provide it to the farmer, that he can use it effectively and safely and make a profit by using it, and at the same time you can sell it to the farmer and you make a profit.

[73] Q. What about the economic investment that is involved in a thing like that?

A. Oh, the economic investment is substantial. In the first place, you have to put together a highly trained complex scientific team. We think that the scientific team should have somewhere at a minimum of a hundred and fifty to up to five hundred or more scientists in order to be effective. It takes you a certain number of years just to assemble and get this scientific team functioning. It takes you a certain number of—oh, a couple of years or better to just identify the key targets that you must search for. You've got to get facilities and equipment for them. You've got to generate a procedure so that—and if you find a compound, from the time you find the compound it's going to take you so many years. And it might take you anywhere from one to ten years or longer to find a compound which you can then start commercialization.

So by the time you actually are able to sell your first pound, forgetting about building the plant or the cost of materials, you have got a substantial investment. So you've got to make a commitment to the long-term. And most pesticide companies that got into the business by virtue of this were not profitable the first several years that they were in business.

Q. What sort of anticipated return on investment do [74] you have in terms of the target that you look for to solve?

A. Well, you want an extremely large return on investment for the ones that's successful, because it's not only got to pay for the enormous investment of that particular compound, it's got to pay for the nine thousand nine hundred ninety nine losers. If you're maybe commercializing only one out of ten thousand, you still got to synthesize the losers and go through all of that. That eventually has to be underwritten by the one winner.

Q. And in synthesizing—or I should say in commercializing one out of ten thousand, which I think you said is what Monsanto accomplishes—

A. Yes.

Q. To your knowledge, how does Monsanto rate among the other companies in that sort of success ratio?

A. Several of the companies have used, over the past, a numbering code for their coded compounds somewhat similar to Monsanto's. We number our compounds consecutively. Lasso was CP 50144, fifty thousand one hundred forty four. Roundup had still a much larger number. Based on that—for instance Baker's Sencor was 94337. They had synthesized and screened ninety four thousand three hundred and thirty six compounds for a herbicide before they hit on Sencor. And that was their first. Based on various industry estimates and my estimates, I believe that the industry is hitting on [75] about one out of twenty thousand. We're hitting on about one out of ten, one out of ten thousand.

Q. Now approximately, annually, what does it cost to carry on this R and D program you're talking about?

A. Well, of course the cost depends upon the scope of operations. Back in the 60's our annual research—in the late 50's, early 60's our annual budget for research and development combined was probably in the range of anywhere from three to ten million. And it increased every year. I think our annual research budget for 1981 or 2—I

don't know whether it's this year or last year's, but at any rate, I think its fifty nine million dollars for research, and probably somewhere in the range of ten to twelve million dollars for development. So we're now expending somewhere between let's say sixty and eighty million dollars in the agriculture company for research and development for agricultural chemicals.

Q. What are the reasons for the increases over that period of time?

A. Well, there are a number of increases, inflation obviously. But the complexity of the scientific procedures, the cost of equipment, because of the more extensive methods of analysis of chemicals that has increased by a factor of-since the sensitivity of analysis has increased by a million. So where we use to run it with a piece of equipment that [76] would cost say ten thousand dollars, we now might have three hundred thousand dollars in a piece of equipment to measure a pesticide. That has entered into it. The fact that as new pesticides are brought on the market there are new standards which you now have to beat. When we brought on Lasso we only had to beat the level of excellence that was out there in '65. For the people that now want to beat Lasso they have to bring on a compound that is better or equal to Lasso. So that the competitive standards are higher.

And then superimposed on all of that is the regulatory requirements are far more complex. There are more of them, and they take longer to do and with any given—any given requirement. Whereas we use to do ten yield studies, we might now do forty. Where we use to have to do four residue analysis, we might do eight. And when we do the eight instead of just measuring at the time of harvest we now measure at four weeks after the crop emerges, at eight weeks, at silage, and at harvest. So that it blossoms out to become a far more complex costly timely procedure than it was.

Q. Does the increase in technology with respect to detection levels have anything to do with that?

A. Oh, substantially. This is the point I was making earlier. When we first came out with a compound for corn and soybeans in 1956 called Randox we were very happy because we had a method of sensitivity that was around one or [77] two parts per million, which in turn was better than anything even possible four years, five years before that. The next product we came out with we had to go to tenths of a part per million. Now we're routinely going to hundredths of a part per million. And in many cases we're easily into parts per billion. And when you increase that sensitivity by a thousand to ten thousand to a hundred thousand fold, the cost of equipment to do that increases by a great deal.

[90] Q. (By Mr. Heineman) Dr. Carpenter, let me ask you now if you would discuss the risks that are considered by Monsanto Agricultural Products Company in determining to develop a particular pesticide?

A. Well, the biggest risk represents, as I look at it, [91] a risk of pursuing losers. And if I could pursue that point, as I indicated, one out of ten to twenty thousand—and for the purpose of this you can take either one you choose—you only have that one winner. But you don't know which one it is, so you've got to devise a procedure by which you can identify the losers and wash them out and get them out of the way so that you can then work with the winner.

The Court: Like an Edsel?

A. Well, hopefully better than an Edsel. We have had our share of Edsels too. But usually what you do is, the end of a year—if you're screening anywhere from three to five to eight thousand compounds a year, usually at the end of the year you've got about ten of those compounds left that you think are pretty good. You're then looking at those ten and you're saying that on one hand that's all I got left that I spent forty million dollars for, in so many words, at thirty or ten or whatever you spent on your research budget. And so to that end you're saying

I'm obligated to see whatever I can do to find those, a winner for those, a place to commercialize those. On the other hand, in all probability there is only one of them that's a winner. And the sooner you make a decision to get rid of those other nine and devote your resources to either looking for the winner that's there or going back and starting over, the better off you'll be.

Now if you say well. I'm going to consider them all [92] winners, you have to start what I term a number of clocks running at the same time because of the time lag. And I can get into this in more detail later. But for instance, without any delays at all to be absolutely as efficient as you can be, it takes you somewhere between forty eight and fifty six months to complete the toxicology studies if you say I'll do nothing, without stopping. If you're going to develop a good process to make this in multi-million pound quantities, from the time you have somebody that knows how to make it in a test tube until you can make it in a plant like down here at Queeny, it's going to take you anywhere from three to six years to develop a process, try it out in a pilot plant, get the capital, build the plant. And the same goes for all these others. If you do all those things consecutively or simultaneously rather than try to do them consecutively, you never get to the end. So you have to start doing all those things at once.

And then the amount of money you start spending to make sure that you're doing all those things at once so you can have commercialization, registration, as soon as possible, the expenses become inordinate and the ability for you to make a proper decision on whether to stop and drop that loser or near miss, and whether to continue on, represents the single biggest risk and probably the single biggest cause of failure of companies, having to get out of the business. [93] They were not able to separate out the near misses from the winners.

And you can lose on any one of those. If the toxicology is not right, regardless of the process you lose. If the toxi-

cology is good and it's going to—the cost is inordinate per pound, you lose. If the production is not consistent year-end and year-out with the farmers, yet you've got good toxicology and it's a cheap product, you lose. So you can lose on any one of those tracks. And you have no choice but keep them all going.

So the ability is to take science, experience, and sales and be able to develop that technique for identifying winners and eliminating losers and doing it in the most effective way possible.

## By Mr. HEINEMAN:

- Q. Now are some of those techniques involved in developing the data, that is, the data that is submitted to the Environmental Protection Agency?
  - A. Yes, they are almost inherent in that.
- Q. And in the data that is submitted to the Agency in support of a registration, are those techniques set out?
- A. A number of them are part of the data submitted to the Agency.
- Q. Now the potential marketsize of the product that you're—or the target that you're looking for, is that a risk that is taken into consideration by the company?
- [94] A. Yes. If you were wrong on your assessment of the marketplace, whereas, you thought a market was big or growing and in turn it got smaller or disappeared, you could have a technical success and a commercial failure.

Monsanto's Edsel was—we had a product for a crop called safflower back in the late-50's and early-60's. It looked safflower was going to be the coming oil seed crop. It was going to go all across California and the Northwest, and it was going to be a big acreage crop, And we found a product that worked for it, and it worked fairly well. And we got it cleared except that the bottom fell out of the oil seed market. And the safflower acreage, instead of doubling or tripling, went down to about one-fifth of what it was. And we had no available market. The volume dropped off to where our cost per pound quadrupled. And the more we sold the more we lost.

- Q. What is the name of that product?
- A. Lambas. It took lambs quarter or weed out of safflower, so we called it Lambas. And that was our Edsel.
- Q. Now is there some consideration with respect to the availability of raw materials?

A. Yes. Not only do you have to make the chemical itself, but in many cases you've got such a new area of chemistry that even the raw materials or the intermediates are not available in sufficient quantity. In the case of [95] Roundup we require a phosphorus intermediate in large quantities. And the amount that we needed was more than the total world supply of that chemical for all uses. We had to go to another company and persuade them to increase their production capacity so that they could supply us the intermediate so that we could make the material. And that sounds like a fairly easy situation because anybody is glad to have a guaranteed market. But if they're going to bring their plant on stream in time for your registration, they've got to be persuaded to start building that plant three years or more before you ever obtain your registration. So you've got to persuade them to bet the come also, so to speak, because-

The Court: Anybody here who doesn't understand the last phrase?

A. I'm sorry, your Honor.

The COURT: That's all right, I know what it means. You can bet the field or you can bet against the roller or you can bet on the come, which means you're betting with him normally, except for some crap tables I've seen. And this may be apropos to the situation, but there's an old saying down in the hills where I come from, just before you do I bet you don't. Go ahead.

By Mr. HEINEMAN:

- Q. All right. What is the time involved, on the average, in terms of Monsanto's experience, [96] from initial synthesis to full commercialization?
- A. We have had approximately ten products that we have registered with EPA as herbicides from 1956

through the present. Obviously as we register those throughout the years the requirements have changed. But in today's, and since the mid-70's on, it's been our experience that from the time we see the product the first time until the time we had our first full registration that accompanied the tolerance, is six to eight years.

Q. When was the last time that Monsanto discovered a new winner?

A. Our last new product was Roundup which was commercialized for non-crop use in '75, and for full crop use for several crops—not for full crops but for several crops, in 1976. So it's been six years.

Q. Are there any changes in the technology in agriculture that can effect the success of a commercialized pesticide?

A. Yes. That has a substantial impact. If crop patterns are shifting, for instance, if they go from full row beans, soybeans planted forty inches apart to narrow row beans or to broadcast or drillbeans that you would do with small grains, those products that were based on treating a portion of the field called ban treatment because of the high price, you reduce the cost by doing that. If all of a [97] sudden soybeans switched to where the only way you can apply the chemical is broadcast it and thereby price it out of the market, then that product will not succeed. So that here's where a technological change, the way they plant soybeans, could have an impact on a product.

As we go to conservation tillage in corn by preserving the soil, keeping the soil runoff, leaving the trash and the plant debris on the surface, there are those chemicals that will work only on a very smooth, well-prepared soil bed where there's no trash or plant litter. If you have a substantial number of acres then that have this trash litter on there, then this product no longer has a viable market on those acres, and that will impact the future of that product.

Q. How about in terms of tillage or cultivation or development of new agricultural equipment?

A. That will have an impact in this conservation tillage. It will take different types of seeders to cut through that trash. And if those seeders are unavailable the concept doesn't work.

So you can lose by changes in equipment, change in weed controls in the weeds that are out there. As the people have gone to less and less cultivations we've gotten different types of weeds that were there when they cultivated a lot. Some of the old chemicals controlled the weeds that were there. Now that we've had a shift in the weeds spectrum [98] these chemicals don't work anymore.

The Court: What you're saying is the old practice of checking corn is long gone?

A. Yes, sir; yes, sir.

By Mr. HEINEMAN:

Q. So, as I understand your testimony, Doctor, there can be changes in the pests themselves?

A. The pests themselves can change. With insects, of course, resistance is well documented with everybody knowing that DDT doesn't kill the housefly anymore, and so forth. With the plants, with herbicides, it's although resistance has been documented in a one or two cases, the big shift there is changes in weeds. In the Midwest when they were growing corn right after World War II there were broadleaf weeds like pigweed and lambs-quarters and so forth. And the D's and T's did a wonderful job, but as they killed them the grasses came in behind them, the crabgrass, the foxtail, goosegrass and what have you. And the new materials would not-the old materials, the 2.4-D's and 2,4,5-T's wouldn't control them. And they started a downward decline and eventually essentially no longer are a factor in the corn market and then you needed a new material that will control grasses. But when you start looking for the new material you better figure out is that going to be a problem twenty years from now. If you look for it in '52 will there be a grass problem in 1972. [99] Q. All right. What if anything have the changes in the regulatory requirements had to do with the considerations that the new product committee would think about when they were deciding whether to commercialize a pesticide?

A. Well, two things immediately. The first is the time lag. In other words, it's now taking longer to generate the data. And by the large, at least certainly in the period of the late-70's, the period in which the petition was under review by the agency was much longer. So that you got stretched out two ways. The time it took you to get the data and the time it took the agency to review the data.

In terms of expenses, it obviously cost you more to get that data and the risks became higher that you were going to succeed. What that did in turn then was to say, I will use a bigger denominator. In other words, where I might could, at one time, commercialize a product for vegetable crops for tomatoes or carrots or cabbage which are a few hundred acres, you now no longer can commercialize a product for that use. And you now say I'm commercializing one for potatoes with a million acres, or dry beans with a million or so acres. And now you're saying I better have a product that I need that has a ten million acre potential. So you change your commercial target or you change the minimum acceptable commercial target by virtue of the increased cost and the increased risks.

[100] The COURT: Just a minute. Let me ask one question here. Let's talk about Roundup and let's assume that, for whatever reason, the data is disclosed not by you but by EPA or whoever.

A. Yes, sir.

The COURT: From what you testified I gather that the hit or miss proposition is controlled, at least to some regard, by the ability to manufacture and process, etcetera, etcetera?

A. [Nodding head.]

The COURT: Now does the data infer or give to competition any suggestions as you which way to go from the standpoint of raw materials, productivity and things of that nature? A. That part, the formulation part and the manufacturing process is held confidential under the current laws. That is not to be released. What is—

The Court: Do they even have it? They have it though, do they not?

A. Yes, they do have it. We submit that routinely as part of our registration procedures. And it is in the file, but that's in the law that it is not to be released. What is in the file though that gives people the lead is the method of analysis, the procedures we use that would allow someone, if they so chose, to take our procedures. [101] And either one, use our techniques as a means of increasing and using that in their own research facilities, or two, taking the data and using it in other countries; or thirdly, to take the data and use it in—in terms of use as opposed to disclosure—to use it in support of their own registrations

The Court: Fifteen minute recess.

[Whereupon, the trial recessed for approximately fifteen minutes, after which time the following proceedings were had.]

The Court: Proceed.

Mr. Heineman: Thank you, your Honor.

By Mr. HEINEMAN:

Q. Just before the break we were talking about the things that can be derived by virtue of disclosure of Monsanto's data to a sophisticated observer, let's say, and you were beginning to discuss that subject. Could you elaborate on it, please.

A. Well, perhaps one of the best ways to put it in prospective is that there are a number of companies out there that are extremely effective in this business, Monsanto being one. If I could see the equivalent of that data over there, or my scientist could see the equivalent of that data for Ely Lilly or du Pont or Dow, we think we would be privy to some extremely useful, extremely sensitive information for [102] the other company instead of seeing what they would see if they saw ours. I can say

that I would certainly be ahead of the game if I saw theirs, specifically in the area of metabolism in which you determine how a product is broken down in the soil or in the plant.

Q. When you were discussing that the successful candidate must pay for the nine hundred and ninety nine [103] unsuccessful candidates, what is the total amount that Monsanto has spent from 1960 through 1981 in developing those successful candidates?

A. So far we've spent over two hundred and fifty million dollars.

Q. How many companies with an investment of that nature, how many companies are involved today in discovering and producing new pesticides?

A. It's probably less than twenty thousand. There's probably three or four German companies, one or two Swiss companies, one British company, two or three Japanese companies. And then the rest of them are in the U.S. And there are probably eight to ten U.S. companies. And most of them probably have an effort that is less than that, or in that range.

Q. Now let me get in for a moment, if I may, to the competitive nature of the pesticide market which you've been discussing. Are there suitable alternatives in the marketplace to Lasso?

A. Yes, there are several good products by some of our competitors for virtually every use of Lasso. We now have developed a label to where there are over two hundred different ways a farmer can use Lasso. When you figure out the ways he can apply it, when he can apply it, in what crops and what other products he can mix with it. And we have [104] several crops, corn and soybeans, peanuts, cotton, a number of other crops. And in every case there is at least two and probably four to five competitors for that use.

- Q. Now while I'm sure that you believe that the Monsanto product is superior in each instance, do they compete for that market in each instance?
  - A. And quite effectively.
  - Q. Now do you run into any imported products?
  - A. Yes.
  - Q. Can you describe those for the record?
- A. There are several foreign companies that have extensive U.S. agricultural operations. Bayer of Germany has a company called Mobay.

The Court: That is extensively advertised right now; is it not?

A. Yes, sir. And a product called Cencor. For many vears they made that in Germany. Not too long ago they built a plant in Kansas City. A German company Data Chef sells a product called Basogram and several other products. And the last time I knew about their manufacturing procedures, all of those products were manufactured in Germany. Ciba Geigy, a Swiss company, has two key products in the U.S., two herbicide products, one of them Atrazine and the other one Duo. Atrazine originally was produced in Switzerland. It's now produced in this country and has been [105] for several years. But Duo has been, and still is, I believe, manufactured in Switzerland. ICI, a British company, had a product called Paraquat. And that for a number of years was marketed-or has been marketed here. For a number of years was produced in England. More recently they have a plant here in the U.S. But yes, foreign imports are a factor.

By Mr. HEINEMAN:

- Q. Do you compete with these companies overseas as well?
- A. Yes, we do, quite heavily. The competition if anything is greater, Australia, Korea, Japan.
  - Q. And now China I guess is developing?
  - A. And now China, yes.
- Q. What is the effect, if any, of disclosure of your data in terms of your foreign competition overseas?

A. Well, in a substantial number of countries that are key agricultural markets, they have neither the same regulatory procedures nor the same patent laws. In fact, in a number of countries, the patent situation is deteriorating, or are virtually nonexistent. In Mexico, for instance, you have three to five years and you have to put in a—you have to go through some step of manufacture there. The situation is similar in India which obviously is large in the rice market. In some cases they do little about checking as to the source of the data. So that once a company were able to get their hands on U.S. data that was submitted for [106] registration here, that data could be used to register in another country regardless of what you might think about it.

And even in those countries where we might have a patent it is extremely difficult to pursue a patent violation. We have been attempting to get a Lasso patent in Israel for thirteen years, essentially the same patent that is issued in every other place. And we have been unable to do so. The Hungarians have just openly violated our Roundup patent in a number of countries and have made and are making Roundup. And we pursue it as vigorously as the law will allow in those countries; but nevertheless, having a valid patent does not preclude or exclude those people from getting in.

So by virtue of having our data, they can utilize it in other countries.

- Q. Now by utilizing it you don't mean they're just referencing the fact that you have a registration in the United States?
- A. They're actually taking the data itself, in some cases, or they can take the data itself I should say—take the data per se and cross out Monsanto and write in Chemoplex of Hungary, and go register the stuff.
- Q. Now in terms of the nature of the data that we're talking about, can you describe it for us generally, what is it that Monsanto Company submits in support of a registration, in very general terms, initially?

[107] A. Let me see if I can block it off into about five general areas. Let's first start with the most obvious. We have to—resubmit efficacy data that shows how the product is used to control certain weeds. How does Roundup control, what weights it should be used, when it should be used, how it should be applied, how much water, how consistent is it over how many years. And we do this working with universities and our own data. Closely tied with this, if there is a crop you must show crop safety as well. If it kills the weed at this rate, is it safe for the crop at twice that rate or three times that rate. What happens if you apply it too late or too early. All these things to determine what the crop safety is so that you can put appropriate statements on the label for the user.

Then working our way back, the environmental information, what is the fate of the chemical in soils. We look at a number of different soil types under a number of different conditions to determine how long does it persist in the soil. Does it move in the soil under heavy rainfalls. Does it stay around too long if it's been extremely dry. And these are very, very thorough experiments going over several years. Because we're required to do all the way from chemical analysis to coming back and growing sensitive crops.

To determine its safety on fish and wildlife there are [108] a number of tests that you must run on various fishes, on things like quail or pheasant or what you to determine its safety there. What happens if the quail ingest it. In some cases, depending on if it's an insecticide, what happens if the quail are in the spray pattern. What happens if the stuff runs off into the water.

Then we move into the metabolism studies, and then you must demonstrate what happens—what is the breakdown product of the material in the plant, in the soil, and to the extent that you can in people. Now obviously you use animals such as a cow or a rat or a chicken in which you feed them amounts of the material in radioactive

form where you can trace it in terms of its breakdown products. Because once you have determined its breakdown products you can then develop a method of analysis for the parent material, the original chemical and the breakdown products to determine how much of it is in the food or the feed and so forth by very sensitive methods.

And that leads you further into the toxicology. There is something-I think the last count bears something like forty different toxicology studies that we run starting with what we term acute. What is the-what amount in a single dose will kill the animal, to fairly short-term feeding studies like feeding large amounts for a month to feeding additional amounts for ninety days to feeding the material [109] for a lifetime of the plant-animal, to going through three generation studies. In other words, if you feed it to rats for several generations you see that each generation is able to give birth correctly and the progeny to the extent that we can determine, are normal. And we measure and observe the generations for any abnormalities, to the so-called chronic mouse and rat studies which are typical ones used that go for twenty four to thirty months. And in all of these studies, extensive pathologies are done, gross. We study behavior, we keep records on the weights, the feed consumed and so forth. Incidentally, probably the field of toxicology has grown in terms of skills more rapidly than any other one. And it's in part due to some material errors made by a laboratory that caused substantial improvement in toxicology.

There is a laboratory, IBT, that did a number of studies for the Government and for the industry, certainly for a lot of our studies. We found out they were doing extremely sloppy work. And as a result of that extremely rigorous standards have been set up on how to conduct toxicology. And so its improved. But at any rate when you then have the toxicology you can determine the effect on animals, both long-term and short-term. And you know how much is present, and you know how long it's going to be there,

and you know how much you need to get done, and you know how much the [110] applicator is exposed to, or the grower exposed to, the farmer and the consumer. Then your regulatory agency can then make the appropriate determination to see if there is sufficient safety for the product to be cleared. So you put all of these together and that represents the main thrust of a petition.

Q. Now all of that data that you submit in support of a registration for a compound, what is your understanding and what is the understanding of the product committee and the Registration Department at Monsanto Company, and the Ag Products Company, as to how much of that is protected from disclosure under the 1978 amendments to FIFRA.

A. Well probably the best way I can describe it, the stuff setting over there on that cart is all the stuff—all the registration data that's been submitted for Roundup alone since about 1973 or '74. That is a whole bunch of uses. The two pages that are open here on this one, these two pages on this petition—which is the formula, and there's a couple of pages on manufacturing data—out of that stack of tens of thousands of pages those are the only two pages, plus the manufacturing, maybe a total of four pages that is held confidential. The rest of it, according to my understanding of the Agency's interpretation of either 3(c)(1)(D) on use, or section 10 on disclosure, all of the rest of that would be available under those particular sections.

[111] Q. Let me hand you what has been marked for identification purposes as plaintiff's Exhibit Numbers 7(a) and 7(b), and ask you to examine those and identify them for us, please.

A. These are pictures of our registration manager, Dr. Serti, who reported to me while I was Director of Environmental Operations, with the Roundup data that has been submitted to EPA for various uses. And it's the same volumes that are shown here. And all of this data,

with the exception of the two pages I indicated, would be available, as I indicated, in section 3 and section 10.

Q. Now if you look at one of those photographs it shows some cabinets in the background with locks on them?

A. That's right, the one which is a head-on photograph directly to the left of the stack. This is—and to the right also you can see the filing cabinets, both the vertical and drawer type where we store our data. And as you can see in our registration area within our agricultural products building we do keep it under lock and key.

Q. Now could you tell us, for the record, a little bit about Roundup; and apply the criteria that you have discussed in terms of target and synthesis and analysis and development to the Roundup situation?

A. We identified Johnson grass as a major target and objective of our screening program in 1952. Every compound that we synthesized we look for to see if it would control [112] Johnson grass. We came up with a couple of near misses in the mid-60's, but essentially did not discover an acceptable commercial product. In 1969 we discovered Roundup, which was seventeen years after we had started looking for a solution for Johnson grass control. In 1974 we got a non-crop use; in other words, for use on railroads and highways and industrial sites.

The Court: Levies?

A. Sir?

The Court: Levies?

A. Yes, Sir. No—well, levies are kind of interesting. You can spray on the back side of the levy but you can't spray on the front side of the levy. And that sounds a little bit unreasonable. But in point of fact—

The COURT: The reason I asked the question, prior to getting on the bench I represented a drainage district. And the members of the district, the farmers within the district, if they saw one sprig of Johnson grass the reaction was immediate and violent. Go ahead.

A. Most farmers feel that way about Johnson grass. But when we registered our first crop use in 1976, twentyfour years after searching, and in 1982 we now have a number of uses for all sorts of different crops, and market it in a number of countries. But the largest use that we think will be the largest use that we will have we still have not [113] cleared, we think the largest single use will be for control of weeds in aquatic situations including Johnson grass, and a number of others for control of irrigation ditches, drainage canals, lakes, recreational areas. And we still have not received that. And it's now thirty-one years after we started looking for the target.

So it's a long-term commitment and the risks are substantial. And we are now putting in more technical resources, both research and development. We now have more technical resources applied to Roundup than we did when we first had our major initial technical effort from '71 through '74.

By Mr. HEINEMAN:

- Q. Have you applied, or has Monsanto Company applied to the Environmental Protection Agency for clearance with respect to aquatic uses?
  - A. Yes, we have.
  - Q. And when was that application submitted?

A. I'm not sure of the exact date. It was somewhere in the late-70's. It could have been—'78 is probably a pretty safe bet, but I'm not sure of that exactly; but it's been four or five or six years. We tested first on aquatics in 1970, and we have been running tests for thirteen years before we obtained label approval.

[114] Q. (By Mr. Heineman) How exactly does Roundup work as opposed to other herbicides? What is it that makes it unique in terms of Monsanto's estimation of it.

A. We think it justifies the term unique several different ways. First of all it has an outstanding environmental impact in terms of safety to wildlife and safety to things like honeybees and so forth. It also has a good human toxicology picture. It's somewhere between—much safer if ingested than say an aspirin in terms of accute toxicol-

ogy. [115] But most especially, it does the job for the purpose intended. Applied to the Johnson grass, it moves all the way down through the leaves down through the stalks and down into the rhizomes of the underground fleshly parts of the plant, all the way to the very tip. And if the rhizome has a grain part extending above the ground, it will kill it. It will translocate down. It's extremely consistent, and it not only works on Johnson grass it works on quack grass, which is the Johnson grass of the north. It will work on nut sage or nut grass, as they call it. It will even work on woody species like wild brambles and woodrose, and has a broad range of activities. And yet, as soon as it hits the ground, touches the soil, it's completely bound to the soil surface so that you can come back and within-and we've done it in plants. and planted the most sensitive crop you can think of where you have just sprayed Roundup, such as lettuce. and it's completely safe. You can come back in and plant. Or conversely, another thing I'm saying is the soil microbiology, the soil microbes, the bacteria and other organisms in the soil chew it up into harmless components very quickly. So for a collection of reasons it kills the weeds, it's safe on people, it's safe to the environment, it's an extremely flexible tool for the farmer. They have developed what they call wipers in which they can just drag a bar across the top of the soybeans and take out Johnson grass, volunteer corn, [116] or some of these other things. Extremely flexible for the farmer. Its use in tea in India. to rubber in Malayia, to coffee in Brazil, to wheat in England. It's been a unique product.

Q. Do I understand you're saying that it takes care of perennial grasses?

A. I guess I overlooked the most obvious.

The COURT: He didn't use the word perennial yet.

A. A number of herbicides will take care of annual weeds, those that germinate from seeds every year. Lasso will do it. Our competition products will do it. But very few if any will effectively and consistently kill the peren-

nial weeds, those that live from year to year to year and keep reproducing from fleshy underground parts or from stems, or trees themselves. And this product does as consistently for the perennial weeds that a number of products would do for annual weeds.

## By Mr. HEINEMAN:

- Q. How is it that Monsanto Company has learned the mechanism by which Roundup works within the plant? Is it through the metabolism studies and things that you have done?
- A. Yes. We have done a substantial number of metabolism studies to determine the effectiveness. From the metabolism studies we can do a number of things. We can determine [117] if there's anything we can do to improve Roundup's effectiveness. Do we need to change the wetting agent and surfactant, can we change the timing, can we change the rate. And indeed, we have done some of those things to lower the amount that the farmer has to use substantially.

We can also use that as leads for additional, possibly better products than Roundup, new chemicals, not successful—non-successful, but nevertheless, we looked at several thousand. It gives us all sorts of insights into how it works, what we should be doing to build the next molecule, and how do we make the present compound work better.

- Q. Have your research scientists done any radio labeling to prove the translocation and enhance the metabolism studies?
- A. Yes. We do that routinely. And this consists of making a radioactive version of Roundup and applying it to the plant, and then measuring the radioactivity. And we do this by extremely sophisticated measures. And we're certainly among the leaders of that particular technology where we hook together a number of different scientific devices including infrared beta cameras, mass spectrophotometers, and gas-liquid chromatographs, and so forth are hooked into a computer so that we can deter-

mine precisely what the hunk of the molecule is we're looking at to a greater extent than has been done before. [118] Q. And do I understand correctly that the information which you have just described as having been generated on Roundup is included in the data submitted to the EPA?

A. Yes.

Q. And that it is not among that which is protected by your understanding of FIFRA?

A. No, it is not. And even though a person were not trying to get his own verison of Roundup labeled, if a person were not utilizing that technique, if they did not have the skills and facilities to do that, then they would see that. And if they had a completely different chemical that would compete with say Roundup or Lasso, then they could utilize that technique to speed up their registration time, so that they would be a competitor sooner or they could do it with four scientists rather than eight, or in essence, reduce the resources that they were having to use, and use those resources then to compete with us in still another turn.

There's all sorts of ways they could use that including registering their own version of Roundup either in this country under section 3, or getting their hands on it for another country through a section 10 disclosure.

Q. You mentioned the factor of time. What is the importance, if any, of time in terms of commercializing a pesticide?

A. I don't believe it's possible to overestimate the [119] value of time. We spend a great deal of our time as management trying to see what we can do to compress the time needed for identification of targets, needed to obtain the data for registration, trying to figure out the most effective way to present it to EPA so that they can be most effective and less time consuming in making their judgments and continuing on.

From the time you get into the marketplace with a new product or new use for an old product, until such time as you penetrate that market to where it's profitable is a matter of years. It isn't the money that you make on years one to five that make a pesticide profitable, it's the years twelve to seventeen, fifteen to twenty. That's when you've achieved your market penetration. That's when you've reached a steady state in terms of amount of resources you've had to put in there. That's when your manufacturing plant is finally running effectively and efficiently at the lowest cost. So that by the same token, if you get there sooner you got that edge on your competitor. If you get there in three years and he gets there two years later, you have got two years in which you're getting your product accepted by the farmer. You're learning more about your product under farmers' conditions; that old [saving] there's nothing true about time is money. It's just with us it's virtually everything.

Q. Do you have a practical example that you can describe for the court in terms of Duo, for example, as [120] compared to the Monsanto product in terms of time?

A. Duo is an especially effective competitor for our product Lasso. Duo and Lasso both fit in to the same general classes of chemistry, a class that we called acetanilide chemistry. We came out with our first accetanilide chemistry in 1956 with a product called Landox. In 1965 we came out with a second generation with a product called Ramrod. And then in 1969 we came out with Lasso. the third generation. Each time we came out with a new product, because they were in the same class of chemistry we could be more predictive on how much it would take. what crop safety, what the residue procedures should be, what the metabolism breakdowns were, ways of synthesizing the thing, what we should expect on how to run our tests so that each time we came up with a new product we were more effective and moved more rapidly than we did before. As a result, we, for that reason and other reasons, we were the only company to have an acetanilide chemistry from 1956 until about 1975 or '76, whenever it came on the market.

Ciba Geigy in developing Duo ran into some of the same problems that we did back in 1956. They underestimated the level of residue that was expected and indeed showed up in certain parts of the crop plant, particularly silage corn and sweet corn. They ran into apparently some unexpected problems in their metabolism studies. It is my judgment and [121] my estimate that had Ciba Geigy had the knowledge we did about acetanilide herbicides in general, nothing to do with Duo, but had access to our metabolism, our environmental impact studies, our residue studies and our efficacy studies on Randox, Ramrod, and Lasso, that they could have eliminated a substantial amount of time from their commercialization of Duo. By virtue of them not doing that we were in the market without their competition for another one or two years. And as a result we solidified or further strengthened our position in the marketplace. We had a better chance to observe their product and decide what-how we could compete with them. Because they weren't in the marketplace yet, and their costs continued to increase while they were not selling.

So in this case, the competitor's lack of insight hit them in terms of time. It was an advantage to us, substantial disadvantage to them. And one that would have been eliminated had they had access to data equivalent to that for Roundup. And they would have not needed our formulation or manufacturing data at all. That would have been virtually no help to them.

Q. As I understand your description of when Randox, Ramrod, and Lasso were developed, the data that was generated to obtain their registration was submitted to the EPA prior to 1970; is that right?

A. That's correct.

[122] Q. So that what is your understanding of the FIFRA rule with respect to what benefit would be generated to Monsanto Company with respect to data submitted prior to January 1, 1970.

A. It is my understanding that no compensation would be available for any of that data submitted prior to 1970, and a substantial part of our Lasso data, our initial registration for Lasso which we obtained for the 1969 use season, was submitted prior to 1970. So Randox, Ramrod, and Lasso data would have all been available pre-1970 data.

Q. But you heard Ms. Mayer talk in her opening statement in connection with the provisions of the statute with respect to exclusive use and compensation and all of those things. Would they apply at all to the data you have just described?

A. None whatsoever.

Q. Now you mentioned the ability to expand on uses. And could you tell the Court something about that and in terms of using the information that you presently have in your data to get new uses for the product?

A. When you're commercializing a new product you have a finite amount of resources. And you can only approach a certain number of the uses at any one time. For instances, with Lasso we decided corn and soybeans were the most important. And we selected those two crops. But with that there [123] were a number of different ways that this could be applied. And we only picked a couple of those. We said Lasso can be applied to corn and sovbeans, the surface, without mixing it with anything except water. We then went back and based on that experience and the precious knowledge, we said another way of applying Lasso is to mix it with Atrazine or with fertilizer solution or by flying it on the plane. And each time we do this we work with the farmers and determine a new form of problems, it forms kind of a feedback. We continue to expand our label to where the original label for Lasso, although it was the proper one to obtain, now represents a very small segment of how Lasso is actually used. And all the rest of the petitions containing these other uses represent the most effective and the most common way that Lasso is used.

Q. Why is it that Monsanto Company works to develop from Randox to Ramrod to Lasso to Machete to Roundup and improved uses?

A. Well, obviously we would like to be our toughest competitor. When our product is displayed we would like to display it with one of our own. The competition is extremely tough out there. We came out with Randox in 1956. Within two to three years Ciba Geigy came out with a much more effective product than Randox. We continued to look for ways of improving Randox. We came out with Ramrod, which was a [124] substantial improvement, it enabled us to recapture and do a better job in the market. In the meantime, Ely Lilly, and now Union Carbide then Amchem, came out with two products in soybeans that were extremely better than Randox. We came out with Lasso in '69 which was a substantial improvement over both Randox and Ramrod, and a substantial improvement over the competitor's.

Ely Lilly then had three competitors come out in the late-60's and early-70's that were certainly tough competitors for their product. And it goes on and on and on. In other words, competition drives you in part and you continue to try to have the best product possible.

Q. Who is the ultimate beneficiary, other than obviously the profit to the company, of this research and development?

A. Well, if the farmers have the same quality of product available now that they had in 1970 they would lose in several ways. First of all the cost of those products as compared to the cost of these products are substantially different because these newer products take less per acre. And the total dollar expenditures are less per acre. They would have to use more of them to get not as good weed control. Yields would be off, consistency would be off. And in some cases safety would be off. In many cases, the products are more evironmentally safe or easy to handle. [125] Randox was miserable to work with. It burned, it irritated, and those properties don't exist with Lasso. But

the ultimate benefactor of all of this real hard competition is the American consumer who is paying a lot for his food. But he's paying less than he would if the farmer didn't have effective means of weed control. And he is still paying less percentage for his food than any other country in the world.

Q. As I understand the EPA is not the only agency to whom data of this type has been submitted by the Monsanto Company?

A. That's correct. Although governments—Japan, France, Germany, Australia, virtually every country, every country that I know of where we sell has some sort of registration procedure. And so we, in those countries where we market the product, we submit petitions so it is submitted to these other—

Q. There are state agencies as well, I guess?

A. That's right. State government, state agricultural—well, it depends on which agency in terms of which state. But we do submit—in some cases the states require only the briefest of indications plus a copy of the EPA registration procedures. In other states such as California we will submit the package to them that we would submit to EPA.

Q. What are the opinions that you and the new product committee and the Monsanto Agricultural Products Company and [126] Mr. Reding who chairs that committee, what are the opinions that you have with respect to the development of the foreign market in terms of what it will mean to the American pesticide producer?

A. Well, it's large and getting larger. And it's getting large in two ways. It's getting larger just from sheer quantity as more and more governments are devoting more and more attention to agriculture and therefore are bringing in the modern units, modern components of agricultural production, including pesticides. But as they do so, the percentage of our pesticide sales that go international as opposed to domestic is increasing. So we see it as of growing importance to Monsanto. And of our products

at least two, two out of our three top products the sales are larger outside this country than inside this country.

Q. Which are those?

A. Avadex BW, which is used on wheat and barley in Canada and in Europe and in sugarbeets in Europe and in Australia; and then Roundup which is used in somewhere between sixty and eighty countries. Lasso is larger in this country.

Q. As I understand it, Machete is used only overseas?

A. That's right, except for the so-called section 18 use in Arkansas and a couple of other States while registration is pending.

Q. How did you come upon Machete as a new product? [127] A. Well, first of all we had, as a target, to try to find something for transplant rice. Transplant rice is where they go out and take the young seedlings and stick them into the rice paddy by hand or by a stick, or even by a machine. Whereas in this country all of the rice is planted more or less as you would plant wheat. It's drilled with the seed into the ground. And this calls for a different type of rice herbicide, one versus the other. And Machete 3 a very close relative with Lasso. Lasso was a near miss on rice, but every now and then we would wipe out the rice field, we would kill the rice. So we went back and made modifications of the Machete molecule and found out-or of the Lasso molecule-and found out we indeed did have safety on rice. And we registered it in Korea, Japan, and Taiwan.

Incidentally, Japan has every bit as strict a registration procedure as does the U.S. So it's been registered and it's been registered there for approximately ten years. Incidentally, Lasso has a number of five zero one four four, 5,144. Machete is five two eight one nine, so it came along—it was synthesized about twenty seven hundred compounds later in terms of numbering sequence than Lasso.

Q. Do I understand it has a selectivity feature to it in terms of its use on the rice crop?

A. It's safe on rice whereas the other products were not. And it enjoys—it's extremely important in Korea and [128] Taiwan at this point.

Mr. Heineman: Off the record a moment, your Honor. At this point I'm about to embark——

[Discussion off the record.]

The Court: I have a note here that the agricultural end of Monsanto Company accounted for about seventy percent of its profit.

A. Yes, sir.

The COURT: And then I saw on one of these charts that the agricultural thing only accomplished about fifteen percent.

A. That's of sales, your Honor.

The Court: Of sales?

A. Yes, sir.

The Court: In other words, you make more money in the Ag business per unit?

A. Yes sir, four to five times as much.

The Court: I see.

A. In fact, much to our dismay some of the others have negative numbers.

The Court: Sir?

A. Some of the others have negative numbers.

Mr. Heineman: For Monsanto Company as a whole, [129] unfortunately.

[Whereupon, the proceedings recessed until Tuesday, March 9, 1982.]

## TUESDAY MARCH 9, 1982

The Court: You may proceed.

Mr. Heineman: Thank you, your Honor.

By Mr. HEINEMAN:

Q. Dr. Carpenter, when we broke yesterday afternoon we were just beginning to discuss the nature of the patent protection available with respect to the products that Monsanto has registered with the EPA. Could you give us some indication of the number of patents issued to Monsanto Company versus the number of products that are actually commercialized?

A. We have a substantial number of patents. They're in the hundreds if not in the thousands. We obtain patents on those compounds, new chemicals which do not achieve commercialization, a substantial number of them. Because they are indeed new chemicals and they are patentable on the basis of their chemistry alone, in many cases they're patentable on the basis of their activity even though they're not sufficient to be commercialized. And then finally once you have identified a commercial compound you synthesize, make new chemicals around that area of activity that serves as a [130] patent family for that chemistry. So we have a substantial number of patents, and we have had ten proprietary herbicides.

Q. Now you have talked previously about a sequence of events that occur, many of which take place at the same time, starting with the selection of a target and the synthesis of chemicals. Where in that process does this patent situation you've described occur?

A. A patent—you can have a patent issued over a broad range of that time frame. You can have a patent issued within two to three years, even one to two years perhaps after you've synthesized the chemicals. Obviously that could be well before you have commercialized the chemical. In some cases the patent can actually, for any number of reasons, back and forth between the Patent Office and the company, you can have the patent issued after we have obtained the first registration. So I would say that a two to an eight year range after discovery is not an unreasonable range.

Q. Now in your functions as a participant in the new product committee and in the products development for Monsanto Agricultural Products Company, have you had occasion to be informed and study the problem or facts with respect to the patent application on the candidates that you've studied?

A. Yes. First of all, as a matter of routine in that assignment, I routinely receive monthly reports from the Director of Patents for the Agricultural Products Company. [131] Finally in our decisions, or in our discussions in our new product committee meetings, the status and predicted status of the patent of candidates was routinely considered in our processes.

Q. Now after synthesis, once the product is discovered—and by the product at this point I'm talking about the specific chemical as opposed to what is eventually registered as a product—when a specific chemical is discovered how soon thereafter is the application for patent usually made by Monsanto.

A. Well, as soon as possible you file the application for a number of reasons, one of which is competitive. Regardless of how confidential and how tightly we regard our area of chemistry that we're synthesizing, nevertheless, there are very good chemists in other companies who read the same literature and might have the same thoughts. And in several key product cases the patent application filing dates were as little as a few days apart between one company and the other. And they had no—either company had, to my knowledge, no idea that the other one was working on the patent in question So competitive pressure demands filing as soon as possible, because the person with the first filing date usually historically has the best odds of getting the patent.

Q. Now usually how much of a period of time does it take after discovery in order to make that patent application?

[132] A. It can be as little as a few months.

Q. And has it taken longer than that?

A. It has taken longer in some cases as you have to go back and get things in order to file your patent application.

Q. Now then the application rests with the—to which agency do you submit it?

A. We submit it to the U.S. Patent Office. But in addition there are certain guidelines that you must follow to file in foreign countries as well. Foreign patent estate is very valuable as well. And if you do not file within a given time in certain countries after filing in the first instance, then you do not have a valid application. So you're not only considering what your filing date must be in the U.S., you must see how that stacks up against Belgium, against Brazil, against Japan, and so forth, so that you obtain maximum patent protection on a worldwide basis.

Q. Now to follow that thought for just a moment, the patent life in the United States is seventeen years by law; is that correct?

A. That's correct.

Q. That's from the date the patent is issued?

A. From the date it's issued.

Q. All right. Now how does that compare with respect to the patent laws in other nations in the world?

A. Well, there's no other nation that provides the—[133] any better length of coverage or patent system. There are some that are equivalent to that. Canada is in the same range, more than likely. However, the patent system in some countries is virtually non-existent to being as little as three to five years. So that the patent situation and the ability to have a patent, a workable patent sometimes varies greatly from one country to another.

Q. Now how long does it—in your experience does the patent application rest with the U.S. Patent Office before the patent is issued?

A. A year is probably not a bad number. We've had some that issue very promptly, we've had some that have dragged out for several years.

Q. Now what is the relationship, if any, between the patent development and application process and the receipt thereof, and the registration process?

The Court: With EPA?

Mr. HEINEMAN: With EPA; yes, sir.

The COURT: All right.

A. Well, by and large they're mutually exclusive, except to the fact that if you lose a patent—let's say you get rejected on a patent and you do not have a patent, then it would call for a reassessment of whether you would wish to go forward with the registration process. But the efforts that are utilized to obtain a patent registration are [134] completely separate operations and require different data, different people, for the most part.

The COURT: Well, in a nut shell is it a fair statement that the patenting process is considerably less time and

money consuming than the registration process?

A. Yes, sir, probably by a couple of orders of magnitude.

The COURT: All right. Go ahead.

By Mr. HEINEMAN:

Q. Now you discussed briefly the subject of doing synthesis around the patented chemcial. Would you describe that a little more specifically?

A. May I use the chart here?

Q. Please do.

A. I think it can be seen a little bit better. We have a product called Lasso which was a very important process—product. It has a—it's 2,6-diethyl-N acetylchloride. Now then, this was a compound that we had patented. Anyway, what we can do is when we find that this is an active compound—these are ethyl groups if you will on the 2 and 6 position. Well then obviously you want to know what happens if you stick it at this point, or this point, or this point. Or instead of sticking ethyl groups, what happens if you stick methyl groups or any number of things. And if this is a CH<sub>2</sub>, what happens if—in other words, you can change various things all around this ring and leave most of the others.

[135] Now we synthesize by varying this, this, and putting it in different places; varying this, putting on groups up here on the nitrogen. We made all sorts of changes.

Now in some cases we solved compounds that were onehalf as good as Lasso. Now obviously we couldn't afford to commercialize a compound that was only half as good as Lasso.

Let's say it takes eight pounds of this material where it takes four pounds of Lasso, or four versus two. Now then, obviously we're better off—everybody is better off to commercialize Lasso and leave this on the shelf. But had a competitor found this product, this product would have been worthwhile for a competitor to develop.

Let's say that in general it's one-half as good as Lasso but in one specialized use for say four million acres of a target, it's equal to or better than Lasso. You can't say it's better across the board. The biological activity, the marketplace, the complications of farming are such that it could have found a market niche where it could have competed effectively with Lasso for a narrow segment of the Lasso market. And a competitor could have seen its way clear perhaps to commercialize that product. But if we have a patent on that product we essentially have provided ourselves patent protection for this one. And this is routinely done in the field of drugs, in the field of equipment, in the field of pesticides. In other words, you get what the patent lawyers [136] call a patent estate. And the Lasso patent estate is very valuable to us.

Q. What do you call the additional product that is one-half as effective as Lasso in most applications. Is that an analog?

A. That would be an analog. In other words, it is—in fact, you can have both analogs and homologs; analogs meaning that it's the same in function and you modify some groups substantially. And homolog would be one in which we just put in more carbons here. But we have all sorts of analogs primarily as a part of our patent estate.

Q. When you obtain the patent you obtain the patent to cover not only the specific active ingredient but the analogs and homologs of that active ingredient as well?

- A. The patent for a Lasso or for other product may start off by saying I claim that I have invented a class of compound in which I have a benzene ring. And instead of naming the particular one they will say that is  $R_1$ , and that is  $R_2$ . And they will say  $R_1$  composes all of these chemicals and they will say  $R_2$  composes all of these chemicals.
- Q. Now please be specific for the record and when you talk about R<sub>1</sub> and R<sub>2</sub> what are you describing?
- A. These are the positions on the—two position and six position of the benzene ring.
- Q. Where once you had an ethyl group you will say—[137] we will say not only an ethyl group but its types of groups that might go in that position?
- A. That's right. Now and then they will maybe say the same thing. They will say—and they call these generic formulas, and they will claim those. And that will be their broadest claim. And that's the one that obviously Monsanto or Dupont or Dow or whoever wants to get.

Then they will make other claims down the line and in which they will become more narrow and more specific on their claims until finally one of the claims will identify the specific chemical, Lasso. And in some cases you get the broadest claim that you made. I have a generic formula that will cover literally hundreds of compounds. In some cases you get only a compound, you get the compound itself and nothing else, and that's all you get.

But in addition to that single compound—now once again we go back and even after the patent is issued we continue to look in this area for analogs and homologs and obtain additional patents on those. For instance, once again we say this was the acetanilide family. We probably had at one time two to three hundred patent deals in the acetanilide arena; of which only about four to six actually applied to commercial products per se.

Mr. Heineman: All right, sir. If the Court please, I'd like to mark this so that we can identify these [138] drawings that he might make. And for the record, the drawing

which Dr. Carpenter has just made in terms of the Lasso patent discussion I will label plaintiff's Exhibit 36.

[Plaintiff's Exhibit 36 marked for identification purposes.]

## By Mr. HEINEMAN:

Q. Now can you describe in general terms how the registration process with EPA is different from the patent application process?

A. Well, the patent application process in some cases does call for a certain submission of biological data. You do have to say, if I'm claiming this product for control of weeds you say I hereby tested it and so forth. So if you looked at it this way, if you said you had a circle here and all in this circle included all the data you put for a patent, okay, now you would have to show the chemistry and you would have to be quite specific about how you synthesized that chemical. I took so many grams of this and so many grams of that and I recrystallized it and I determined its purity and its structure by these means. And you would have to give your proof. And maybe let's say you might have to talk about a little activity. And that would essentially be it. And you would have to maybe quote prior history as to why this particular product is unique. You would have to talk about the uniqueness of its and you would have to do the literature.

[139] Q. Do you give any physical properties?

A. You would give melting point and you might put boiling point. And you would talk about its soluble in alcohol, its soluble in acetone. In other words, you would give physical properties.

And by and large all of this is published—and the patent itself, when the patent issues—all of this is published and is a matter of record. When the patent issues it's on the patent itself and is published in the patent. Now if you looked at all of the data that deals with registration then if you drew another circle, what I'm trying to point out is there is a tiny bit of overlap in that data you submit to EPA or other regulatory agent for a pesti-

cide registration, and the data you submit in a patent. There is some overlap. For instance, you obvioulsy submit the chemistry of the material, would be in the same place. And you put—you don't talk about proof, whereas we talk about maybe a little bit of activity in patent, we might submit one or two greenhouse studies that are fairly simple to claim the patent. Whereas in our first Roundup petition for crops, for instance, we submitted twenty five hundred experiments that went on in many cases for over three years.

Q. The latter being to EPA?

A. The latter being to EPA. So efficacy is probably a hundred to a thousand times greater, and maybe even more [140] than it is in a patent. Now so that might fit into part of the overlap here. But the metabolism, the toxicology, environmental chemistry, most of the efficacy, virtually all of the crop safety and the things that are in the non-overlapping part where they're mutually exclusive, number one, represents ninety-nine percent plus in terms of research effort of the total package. In other words, there is less than one percent overlap if you looked at the data.

Q. Between what is submitted to the EPA and what is submitted—

A. And what is submitted to the patent. And further if these were—if the size of the circles indicate the total amount of effort, this circle would probably be at least a hundred times greater.

Q. By this circle you mean?

A. The EPA registration effort takes a hundred times more data and effort than the patent. Now obviously you start with the patent. And it's extremely important, extremely valuable. It's critical. But in terms of total amount of effort, one is substantially more than the other. And the main thing is, except for these little areas in here they're essentially mutual exclusive. The effort, the dedication, the people involved, the whole thing is separate from this, from the EPA's.

Q. All right. Now the patent information that is [141] submitted is disclosed to the public if the patent application is granted?

A. That's correct.

Q. And the EPA information, but for the 1978 amendments to FIFRA, is not disclosed; is that correct?

A. At this point in time speaking for Monsanto data, at this point in time this is not disclosed.

Q. By this you mean the EPA data?

A. The EPA registration data.

The Court: Now you're talking about this amendment. Is that—enlighten the court on this compensation business. In other words, we've got a registration, and assuming arguendo you've got a disclosure, and assuming arguendo that the me-too people, the me-too people or whoever use it. Is that where this compensation comes in?

Mr. Heineman: If your Honor please, may I have the witness describe it? Because he knows a great deal more about it than I?

The COURT: I think that's got a little more to do with the law than some of the things we've heard. I'm not questioning—but let's get into that.

By Mr. Heineman:

Q. Dr. Carpenter, please answer.

A. First of all the data is divided as to whether compensation is available based on the time it's submitted.

The Court: There was none prior to '70; is [142] that correct?

A. The way the law currently reads there is no compensation for data submitted prior to 1970 which comprises all but one—most of the data for all but one of our products. The person that wishes to utilize our data has to write to Monsanto and notify EPA saying we hereby offer to compensate you for your data. He does not have to say I offer you x-dollars or make—all he has to do is say I offer you compensation.

The Court: In other words, he might just buy you a glass of milk or he might buy you a ten course dinner?

A. His concept of what's reasonable is all he has to have in mind. Now then, EPA is obliged by the law without waiting to see, you know, if he says I'll buy you a cup of coffee and you say I want the national debt, well, you know, obviously there's no agreement there. But nevertheless EPA is obliged to register the product for the metooer whether agreement has been reached or not. If agreement cannot be reached then it must be referred to binding arbitration for which there is no appeal.

The COURT: Well, when does this take place? In other words, I assume that the purpose of the binding appeal and the arbitration is to establish the nature and extent of damages, if any; is that a fair statement?

A. That's correct.

[143] The Court: Well, we're getting into speculative damages, we're getting into various rules that apply in court. I don't know about these arbitrators, but if we're talking about the future you can talk about future damages, you can talk about speculative damages, you can talk about loss of business damages. The field is rather wide. And the question is, in your experience—and of course I'm sure both sides will refer to the law as it's written—but it would appear to me that there have been a lot of damage suits down through the history of jurisprudence where the amount involved could have changed substantially, depending on when the matter was presented to the court or the arbitrator. And that's what I'd like to hear about.

A. Well, to my—Monsanto has no experience on arbitration. We have not had a situation—by virtue of our lawsuits we have not been involved in that.

The Court: You're talking about this lawsuit?

A. Yes, sir.

The COURT: Never been involved in previous years on other matters?

A. No, sir. It has not happened in previous years, to my knowledge, prior to the passage of '78.

The Court: Well, then you're not in a position. The Court will have plenty of law in the cases, I'm sure, that counsel will be submitting plenty of that, or have [144] already.

The question is, you have no practical knowledge of what the results of arbitration have been; is that correct?

A. That's right.

By Mr. HEINEMAN:

Q. You mean insofar as Monsanto is concerned?

A. Yes, sir.

The Court: Well of course I'm not asking him to go to American Cyanamid or something like that. They might not have any information either, I don't know.

Mr. Heineman: Well, there may be more public knowledge about that subject. That's why I——

A. Well, the only case of arbitration that I know of, and my knowledge is——

Ms. MAYER: Your Honor, I object.

The Court: Sustained. I was just asking him—we're talking about Monsanto and not somebody else.

A. It has not happened to Monsanto.

The COURT: Go ahead.

By Mr. HEINEMAN:

Q. Now Dr. Carpenter, according to your understanding of the statute for what is the offer to compensate made? Is it for use, disclosure, or what?

A. It's for use. It is not for disclosure.

Q. According to your understanding of the statute is there any offer to compensate at all required in terms of the [145] disclosure provisions of the statute?

A. There is none.

Q. Now if we may talk about, for a moment, this patent data on the one hand versus EPA data, or registration data on the other. When the patent expires is the data submitted to EPA in support of a registration disclosable by the EPA by virture of the fact that the patent on the product has expired?

A. The patent has no bearing on whether the data is—that's two separate issues. EPA—

The COURT: In other words, if you've got a patent beginning in 1960 and a subsequent registration, and the patent expires in '77, has absolutely no bearing on your relationship or the disclosure as far as EPA is concerned; is that right?

A. Yes.

The Court: All right. Go ahead.

By Mr. HEINEMAN:

Q. Now you were discussing previously the various periods of time within which the patent may issue as opposed to when you get your first registration with the EPA. Now would you expand on that a little bit in terms of when those times can occur with respect to one another.

A. Well, by and large there is, because of the length of time that it now takes to complete the registration [146] package and put it together-which is now in the range of approaching six years-toxicology alone is forty-eight to fifty-three months-so by the time you submit the data and get your label back-your first label not your subsequent labels-that can easily be six years and in some cases it's stretched on for longer than that. So that the probability is that the patent is going to have issued based on history of patents issuing and the time elapsed, the patents are going to have issued well before the registration-first registration is granted. So that in essence, by the time you are legally allowed to sell by virtue of the registration, you have lost a significant part of your patent life. And a point I would make here is you never lose the first four years of your patent, you lose the last four years. The first four years you always got. If you get your registration your patent has been going for thirteen years, what you've lost in terms of patent protection while you're selling is year fourteen through seventeen. And it's in those years where you have built up the large sales volumes and so forth, where you have an opportunity to recoup your losses.

Q. Now I think you said that there are occasion, when the patent application may be granted even after the date of the first registration. So for that particular use that's registered you would have the complete patent life?

A. That's correct.

[147] Q. All right. But I think you testified yesterday concerning Lasso and the fact that additional uses have been registered. What is the effect of that in terms of the patent life?

A. Well probably the most important use we have of Lasso right now was developed in 1979, some ten years after we had commercialized, and some seven years after the patent issue. This use, this conservation tillage use is a way of applying Lasso to prevent soil erosion and at the same time give effective weed control. And it probably now accounts for twenty—maybe up to forty percent of our sales in that use. Now we will have—and it is not—obviously that is not a patentable use, but it's part of our registration, our label packaging data. That will have approximately ten to twelve years protection under our patent. Our patent expires, I believe in 1989.

The COURT: Let me ask a question here. If you don't get your registration you don't sell; is that—

A. Yes, sir.

The Court [continuing]: -basic?

A. Yes, that's right.

The Court: But let's assume that you have in your application for registration given certain facts and data which, if disclosed, might cause some problems in a related area.

[148] A. Yes, sir.

The Court: Now I know you all are going to tell me what the law is. I already understood there might be a difference of interpretation of certain facts, and I'm sure there might be different interpretations of what the law provides. But what I'm getting at here is under those circumstances—and you can't sell it because you haven't got it—

A. That's right.

The Court [continuing]: —but is there any disclosure problems in that area?

A. No, sir. They do not—cannot, under the law disclose only after registration.

The Court: In other words, nothing goes until there's registration?

A. That's correct.

The Court: Well, I would like to hear from both sides on the logic of EPA's position in that area. Not testimony, sir, I want—this is one for the lawyers. In other words, and tell me if I'm getting far afield now and don't hesitate, you won't hurt my feelings—but you've got something that's not saleable that might have a bearing. It cannot be disclosed period. But you get something that is saleable where according to this witness' testimony, more than a few hours, a few days, a few years and a few dollars have gone into the testing and the application for [149] registration and everything else. And the minute you get something that has an enhanced value because there is a probable market for it, or at least a possible market, then it's disclosable?

A. Yes, sir. It's a little bit more-in our viewpoint, it's a little bit more frustrating than that. Let's say at such time the data is disclosed to a competitor and at that point in time that competitor can have, for all practical purposes, the identical label that we have, the hundred or two hundred uses that we've developed for that product, at whatever point in time it comes in it can rely upon all of our data to get all of our uses. And it doesn't stop there. We can say okay, you're where we are, we will compete head and head. But we will apply our efforts and we will find even better ways to apply Lasso, more effective ways, safer ways, and we will submit that. And the instant we submit that they say, by the way, I'd like to cite that data as well. So that in essence, you're technology is not compromised, if you will, in my viewpoint, for a given point in time. You can never take your technology and protect it for a product such as Lasso, since it's excluded now from any consideration for data or exclusive use. Under the current laws anything else we do for Lasso, improve it for the farmer, to improve our own economics, or whatever, that data is instantly available for as long as we choose to submit data. [150] And all somebody has to do is say we offered a reasonable compensation; and it's there instantaneously, long before any money changes hands or it gets to arbitration.

By Mr. HEINEMAN:

Q. Now Dr. Carpenter, I'd like to discuss—or I'd like to have you discuss for the record the relationship between the cash flow that the company receives in spending on a product as they're developing it, and then when they start to sell it, when they start to recoup that cash flow in terms of the patent life and the registration?

A. All right.

Q. I may not have articulated that very well; but I'd like you to describe that for the Court.

A. What I'd like to do is try to sketch this out on the board. But before I go up I would say this, the expenses you have-and we'll deal not with the backup but with the expenses of the failures, and we'll talk only about the expenses of the compound itself and in a general philosophical term-your expenses start out in a rather modest way. You've got the expense of the synthesis chemist who in his laboratory makes the compound, and the biologist and the greenhouse that tests it. So that the first year your expenses are essentially whatever proportion. If you tested a thousand compounds and you got a winner the first year in whatever it costs you to test those thousand compounds your expenses might be one thousandth of that. That's a little [151] oversimplification, but it's in that range. But if you identified it as having potential and you started those various clocks running, if you will, then the expenses start to accelerate at a very rapid rate. The other thing if we talk about expenses we ought to recognize there will be no income until you obtain that registration. And for practical purposes, we can use a figure anywhere six or eight years from the time the expenses start until you start getting money back in. So that's the type of thing that one ought to keep in mind.

The Court: Let me ask a question here. Assuming—now assuming you have got your registration.

A. Yes, sir.

The Court: You don't know you're going to get it, I assume?

A. No, sir.

The COURT: Is that the trigger that you're talking about, clocks, is that when the clock starts on building the plant or plants and securing the machinery, I assume?

A. You got to do that ahead of time.

The COURT: The machinery is tailor made?

A. You got to do that ahead of time, sir. It's a rare product that won't call for special equipment.

The COURT: In other words, you're gambling [152] that you get registration; is that what you're saying?

A. Yes, sir. Once again.

The COURT: All right. Go ahead.

A. If we spent this in terms of time, and this was dollars and we took a line, and this was zero, when you're over at that line you're at a break even on any given compound. And if we say one, two, three, four, five, six, seven, eight, nine, ten, the first year you're going to spend a fairly small amount. But if it looks good you will spend substantially more than that the second year. You will go like this, because you're going into more complicated tests. You have now got to have several chemists synthesize much larger amounts for the advanced testing. You're starting some of your toxicology studies. Your process people that are trying to figure out how to make it in a big plant are beginning to take some preliminary looks at it just on a look-see basis, because you got to remember there's probably ten—at this point, this is in a

category of the third year—you probably identified this thing as we're going to go all out on the thing. And at this point in time you start a substantially large amount of toxicology. You're starting your environmental chemistry, your metabolism. You're actually going out to probably dozens, in some cases hundreds of academic cooperators. You have really pulled the plug, and it's going to go even—the line is going to go even [153] further down.

Now then if the third year looks good, at that point in time you probably got to make a commitment for capital investment. You have got to start building the plant, because from the time you decide—now let's just say for the sake of argument somewhere between six and eight, so we'll say that this is the point that you get your first label registration, we'll just arbitrarily say it's seven years after you have found the product, and that means that you had to submit it somewhere say a year, five and a half, because you have got to allow probably eighteen months for the EPA to review the data. That means that—and that's really pushing if because that means you're trying to do a whole bunch of things in five years.

The COURT: Well, does the EPA from the standpoint of their technical approach to this matter, or these matters, do they have the hothouses and the greenhouses and the chemistry labs and a comparable amount of expertise and manpower—or personpower, pardon me—to get into this?

A. They have not greenhouses, they will contract with appropriate academics occasionally just as a spotcheck. For instance, we make claims for one of our products, Ramrod. They will pull a sample, one of their inspectors will pull a sample of Ramrod, have it tested and say you claim that Ramrod will control foxtail under these conditions. Indeed it did prove it, but more importantly not as much biological. [154] They will look at our analytical methods and say, you say your methods will detect this stuff in crops down to this level of sensitivity. Now we want to see if this method is valid. So they have scientists that are capable of doing that. But by in large in terms of

being able to test every product, or duplicate what we did in terms of toxicology, metabolism and so forth, they in no way approach that sort of resources. Spotchecking us and seeing that we're valid is probably a better interpretation.

The COURT: Go ahead.

A. In year three or four then coming back to capital investment, we know from the time that we can make a decision on capital investment-and in many cases, now the last Roundup plant we built, I think, was around sixty million dollars. The first Roundup plant we built was somewhere between twenty and thirty million dollars. Just inflation alone runs it up. But at any rate, that went to thirty million dollars. We know in order to build the plant and get the appropriate permits, environmental impact statement, to get the approved discharges and so forth and so on, the air permits and so on, we're really pushing it if we think we can do all that in three years. So if you say I don't want to put sixty million dollars out into-on the table until I know I got a registration, well, you've avoided the risk but you have delayed when you can actually start making it to three to four years after [155] your registration. Because you don't have a place to make it. So in addition to gambling on starting all the metabolism, toxicology and all these other things, you also have to make a commitment on capital investment.

Now once you start making a commitment on capital investment your line goes straight down. So in essence, what you've got then is, if you would say that your curve then is going to start off kind of like this (indicating), it's going to hit bottom here. But it doesn't immediately jump back up because if you look at sales, your sales start off slow. I remember quite well because the future of our company depended on Lasso. The first year we sold Lasso, in 1969, it just so happened we sold an even million gallons of Lasso. The next year we sold right at two—something less, it was actually about 1.8 to 2 million gallons.

The third year we went to 3.2, and the fourth year we went to 4 to 5. And after that it gets a little bit hazy.

So that even though you've started selling, you've got a pretty slow curve to where you recover. In other words, your net cash flow is going to stay negative long after you have got your registration.

[156] The Court: Did I understand you to say that the Lasso success story, which I assume you call it that—

A. Yes, Sir.

The Court [continuing]: —was the financial increment that saved Monsanto.

A. Yes, sir. Well, let's put it this way. If it hadn't been for Lasso and for Roundup in the last three years I wouldn't want to have to compare what my salary might be or where I'd be. Because—

The Court: I'm not just talking about agricultural——
A. Oh, no.

The Court [continuing]: —I'm talking about the whole business.

A. Well, sir, let me give you some figures. Last year—

The Court: That's the reason I think the courtroom is probably being sealed.

Mr. Heineman: That's part of it, sir.

A. Last year our sales were around seven billion dollars for the corporation. And this is a matter of public record, obviously. The Ag Company sales were around one million dollars, something more than that. If you look at Monsanto's total net profit we returned something like less than five percent return on our sales. And our investment is [157] about the same. Our net investment just happens to be about the same as our sales. So we earned five percent return on investment. If you took agricultural sales out of that, we would have returned less than one percent on our sales or investment.

Now when you look at obsolescence, replacing your plants, allowing for inflation, whatever, you can't sustain

a capital intensive company like Monsanto on one percent on sales. So I'm not saying we would go under, but it sure would be a pretty miserable grim place if it hadn't been for Ag.

The COURT: Go ahead.

A. But in summary, you can say that to recover your net capital cash flow from a given product, looking only at expenses for the registration and for the manufacture and formulation and all of the other company sales expenses, development expenses and so forth, you are several years after. It doesn't make any difference whether you're talking about four, six, or eight, you're several years after your initial registration in sales before you can recoup your money on that particular investment.

Now the other thing to keep in mind is that you have still got all of the greenhouses and all of the chemists and all of the biologists that are still back looking every year at those other nine thousand nine hundred ninety nine. And sooner or later you have got to have enough of these products [158] coming along so that they're well up into here (indicating), that can pay for those failures that you're going to continue to find.

By Mr. HEINEMAN:

Q. At what point in your experience does or has Monsanto tended to break even on a product insofar as just the expenses for that product?

A. Probably the third to fifth year, maybe sixth year depending on what the product was. On Avadex—

Q. That's after registration?

A. After registration. On Avadex we commercialized that product in 1961, '62, '63, somewhere in there; and we miscalculated there on how well the farmer would adapt to our product. And there we didn't get to break even until 1970. As a matter of fact, when we started our agricultural effort in 1952 in the old organic division, we formed the Ag Company in 1960, and we were 1962 or '63 before the Ag Company could show a profit. So that the

total Ag effort had a ten to twelve years lag time before it became profitable.

- Q. If one were to assume that you got your patent in the second year after discovery, and registration in year seven, all right—
  - A. Okay.
- Q. [continuing]: —when do you break even in terms of when your patent life runs out?
- A. Well, if you get it in year two then it goes out [159] in year nineteen. Two plus seventeen is nineteen. And if you're at the break even point at, let's say four years after registration, and you got registration at year seven, then at year—you're at year eleven. So that you're really at a break even point for six years of the remaining patent life. And that is the most optimistic way of looking at it.
- Q. Now of course on occasion as you mentioned, the patent can be obtained at or about the time the registration is obtained?
  - A. That's right.
- Q. So you would break even much earlier in the patent life under those circumstances?
  - A. That's correct.
- Q. Now has it ever occurred, Dr. Carpenter, that there could be a delay in registration?
  - A. Yes, sir.
  - Q. Okay. Has Monsanto had that experience?
  - A. Yes, sir.
- Q. Okay. How much of a delay can there be with the EPA in getting your registration?
  - A. There can be several years delay.
  - Q. Now what do you mean by several years?
- A. Well, we have a product, Machete was the fourth generation of acetanilides. This is used for transplant rice in other countries, that we began selling in about 1970 or '72 [160] or '73 in the Far East. I think we submitted that product for registration in EPA in 1977 or '78, and we still do not have registration for that product.

Q. Now let's assume that you had a couple of years, a two-year delay in registration. Now does that have any effect on the expenditures that you've undertaken, anticipating registration at the seventh year?

A. Yes. Virtually all of the expenses keep going unchecked. Now you've built your plant so you aren't going to continue to build more of a plant. But nevertheless, you have got idle capital, if you will, idle capital charges. The plant is setting there and not running, so there are substantial expenses involved in idle capital. But in addition, the people that you-if this was your first product you have got salesmen sitting around with nothing to sell. You're going to continue—the development crew are going to go out and put out their own tests and work with the university and farmers one more year. You have got the whole organization and all the expenses accompanying them sitting there if nothing else, just all the money you have expected, that is now a negative factor, that is impacting further just from the interest that accrues, you know, you owe it to somebody, if you will. You might owe it internally, but nevertheless the expenses get substantially worse.

Q. Now what does that factor of say a two-year delay [161] in the EPA registration do to your economic curve and the time of your recovery?

A. It deepens the curve, it deepens the curve because you owe more, or you've spent more and then obviously it takes you longer to get out there. Now if you have a competitor, and you virtually always do, who's out there, it means it's going to be tougher for you to get into the marketplace just as it was for say Ciba Geigy to get in against Lasso. It's going to be tougher for us to get into the Lasso—or get into the marketplace with a label delay. Now then that means that what you once projected as a market share, that you were calculating this on the market share, is either going to take you longer to get there or you're not going to get there. So you get caught

two ways. You spend more and you run the risk of not having as big a reward out at the end.

Q. So is it possible under those circumstances that you never do break even?

A. That's right. And then you end up dropping the product. This Machete situation, I indicated a company called Chevron has a product called Bolaro which is a rice herbicide. We have been competing, if you will, in the testing arena with the rice experiment stations for Bolaro for quite a while. Just this year Chevron obtained tolerances and thereafter a registration for Bolaro. Chevron, [162] unless we get our registration some time before the next rice season—and it's almost too late now, the season is on us—Chevron will have a minimum of one year's jump on us in the marketplace. It's a good product, they're a good organization. They will be tough to compete against having that one year jump against us.

The Court: Fifteen minutes.

[Whereupon, the trial recessed for approximately fifteen minutes, after which time the following proceedings were had.]

The Court: Go ahead, counsel.

Mr. Heineman: Thank you, your Honor.

Q. (By Mr. Heineman) Dr. Carpenter, pursuant to your understanding of the 1978 amendments to FIFRA, is there any relationship under the law between the offer to compensate from a me-too applicant and the actual damages or expenses or investment that you have in the product that you have registered?

A. It is my understanding-

Ms. MAYER: Your Honor, I object. I don't think there has been any testimony that they have had any experience with offers to compensate. And I think his testimony will be speculative.

The Court: Well, in view of his previous [163] testimony I'm going to allow him to testify briefly on the matter. Go ahead.

A. The statute does not provide any recipe, if you will, for determination of damages. It merely says that an offer to pay must be made and that if agreement cannot be reached then it must be referred to arbitration, without giving procedures, techniques, or guidelines for determining what if any compensation must be given.

By Mr. HEINEMAN:

Q. Okay. Let me take a moment if I may, here, to have you identify these documents that you have prepared in illustration of your testimony. The first one which we marked plaintiff's Exhibit Number 36, would you for the record state what that document is?

A. In general it was a discussion of how patents are arrived at and the type of patent we have, and how we—why we pursue patents with pesticides.

Q. And it was a discussion of the analogs that are covered by the patent application?

A. Analogs, yes.

The COURT: Pardon me, getting back to the witness' objected to testimony, I understand it to be that there is arbitration, that the arbitration is final and binding?

Mr. Heineman: Yes, sir.

The COURT: And that there is no appeal [164] whatever? In view of the objection I think that that question probably is better left up to the Court rather than the witness. You may proceed.

Ms. MAYER: Thank you.

By Mr. HEINEMAN:

Q. If I may turn then to what's been marked for identification purposes as plaintiff's Exhibit Number 37, would you identify that for the record, please?

A. That shows the composition of the items that comprise patents, the various data that is in a patent as compared to the data or scientific information that is in the registration document package that is submitted to EPA. And I pointed out there is a very tiny overlap between the two areas of endeavor.

Q. All right, sir. And going then to what's been marked for identification purposes as plaintiff's Exhibit Number 38?

A. We showed in general in Exhibit 38 that the expenses involving the registration of a candidate pesticide start off slowly and accelerate to a peak in registration, to the point in time of registration, and that you do not obtain what is used as a term, a positive cash flow, until several years after registration.

Q. Now Dr. Carpenter, there has been a good deal of discussion in the last day or two concerning active [165] ingredients, technical product and formulation. Now for the record would you differentiate between those terms?

A. Let me use Lasso as an example. The active ingredient in Lasso is a chemical called Alachlor, the one whose structural formula I drew on the exhibit. The technical product is the manufactured product that has a certain percent purity, usually above ninety percent, with a certain amount of inactive or non-pesticidal ingredients that are a part of the manufacturing process. So that the technical product is composed primarily of the active ingredient and a bunch of other glop, if you will.

Q. A bunch of other what, sir?

A. Miscellaneous things. The formulation is that product which is—well, actually, you register both the technical ingredient, but you register the formulation and that is the product that is sold to the farmer. And that includes a known guaranteed amount of the active ingredient plus other components that also are identified that give the qualities that you want. You have a solvent perhaps to dissolve the pesticide. You have emulsifiers so that you can mix the two with water or fertilizer solution or some inert carrier, even clay. And usually the formulation is expressed as pounds per gallon. In other words, Lasso is sold as a four pound per gallon formulation. In other words, it contains four pounds of [166] active ingredient per pound of formulation.

We sell a granular form, a Lasso 2 that is fifteen percent active. In other words, for every fifty pound of product you buy in a fifty pound bag it contains seven point five pounds of active ingredients, it's fifteen percent active.

- Q. Fifty percent?
- A. Fifteen.
- Q. Fifteen?
- A. So that the formulation then contains known designated planned ingredients over and above the active pesticide.
- Q. Now formulation, the formulated product is what is even-ually sold to the consumer?
  - A. That is correct.
  - Q. And it contains the active ingredient plus-
  - A. Solvent, emulsifier, carrier.
  - Q. A surfactant to spread it over the weed, plant-
  - A. Right.
  - Q. [continuing]: —or something like that?
  - A. Yes.
- Q. And those are labeled on the label as inert ingredients?
  - A. That is correct.
- [167] Q. Now in connection with the development of a formulated product, how does the research and development department coordinate with the technical services and the various other departments; how does this product move along in terms of development prior to registration?
- A. Well, at the early stages the formulation section studies the active ingredient to determine the best way that it can be applied. Factors that it must consider are obviously safety. You must not use solvents or other materials that are extremely toxic. You must consider the fact that they are registered as inert ingredients with EPA. You must consider costs. You can't use exotic or expensive solvent that would increase the cost substantially.

Primarily you're looking at effectiveness, in other words, how can the pesticide be applied to give the best results for what you intend to use it for. Shelf life, it must be able to sit on a shelf in a farm market store for x number of years and still be active and handle properly. All of these factors must be considered. And as you're going through the preregistration stage you are probably testing several different types of formulations. And you will select one of them, or maybe more than one, to be that which is registered.

Q. All right. Now this comes subsequent to the [168] synthesis stage itself?

A. Yes, yes.

Q. Now, Dr. Carpenter, I'm going to hand you what has been marked for identification purposes as plaintiff's exhibits 4-C and 4-M, and I wonder if you would examine them in turn and describe them for the Court, please?

The Court: Has opposing counsel seen them?

Ms. MAYER: We have copies, your Honor.

The Court: All right. Go ahead.

A. These two photographs are pictures taken in our formulation laboratories, two of our laboratories, which shows you some of the complexity of the work that's done to obtain proper formulation.

By Mr. Heineman:

Q. Now let me hand you next what has been marked for identification purposes as plaintiff's Exhibit No. 4-J, and ask you if you would examine that and identify it for the Court, please.

A. This is one of the shelves of our sample room that contain the samples that are being—in part, some of the samples—I have to make a count there—that are being looked at by our research group at any one time. These can be all the way from batches of process studies to new chemicals themselves. Typically these will turn [169] over at a pretty rapid rate, and there will be several shelves similar to this.

- Q. Now the exhibits you have just identified here relate to the synthesis and formulation chemistry aspect of Monsanto's business; is that right?
  - A. Yes.
- Q. Now subsequent to synthesis of the chemical itself you then proceed into screening; is that right?
  - A. That's correct.
- Q. Now let me hand you what's been marked for identification purposes as plaintiff's Exhibit No. 4-L, and ask if you would examine that and identify it for the Court, please.
- A. This is a typical greenhouse of which we have many, in which we grow the plants for various types of testing. In this case this is a screening greenhouse in which we will look at a large number of plants grown under identical conditions, looking at the impact of the chemical on these particular plants.
- Q. Now where is this particular facility located that is represented in Exhibit 4-L?
- A. This is in our laboratory facilities out at Creve Coeur at our world headquarters.
  - Q. And as well, Exhibits 4-C and 4-M?
  - A. That's correct.
- [170] Q. Those are all located here at the Monsanto headquarters in St. Louis?
  - A. Yes, they are.
- Q. Now what effect, if any, can a minor difference in formulation have in terms of the performance of the pesticide?
- A. It can have a substantial difference. For a change in emulsifier or a solvent, the so called inert ingredients even, if you shift those and you're applying the product post-emergent to the crop, there are some solvents that will substantially damage the crop itself. You get what we call solvent burn. And one has to look at that. If you change emulsifiers, the ones that cause it to mix well with water, and you did not check out the emulsifier to see if it would also handle well in fertilizer solutions, you

get what we call jelly built up in the fertilizer solution. It clogs the farmer's equipment, it won't spray. And in some cases you can actually get a material that can react with other pesticides if you are mixing them, and cause them to not be applied well.

So when we change a formulation we undertake a very thorough study over and above those toxicology requirements which are required by the registration group in EPA. We also have to look at it on a wide range of things, ranging from shelf life to efficacy.

[171] Q. Now at some point there is some effort given in connection with the manufacturing process; is that correct, sir?

A. Yes.

Q. Could you describe for the Court what work is done in general terms in that area?

A. Well, they take one of several different approaches. First of all, you're trying to manufacture in an economical way the highest purity product that you have. Our average assay on Lasso has gone up several percentage points since we first went in there. You're trying to modify the manufacturing process so that you reduce the amount of waste being discharged. In other words, less waste you discharge the better off everyone is. You're trying to modify the manufacturing process to achieve economic gain, a more inexpensive way of manufacturing. In some cases you're trying to eliminate an undesirable impurity that you may not want in there. All of these would be reasons to modify the manufacturing process; and that is an ongoing process. For every one of our products we never stop studying our manufacturing process.

Q. Now what kind of considerations do you have to have in that connection in terms of feed stocks, other environmental controls, those kinds of things that relate to how you develop the manufacturing process?

[172] A. Well, you must be assured of a source of raw materials for the manufacturing process. You must be assured of a continuing dependable economic supply of

those; and you must be sure that the manufacturing process itself must meet the specifications of other environmental laws.

Q. Now let me hand you what has been marked for identification purposes as plaintiff's Exhibit 4-K, and ask you to examine that and identify it for the Court, please.

A. This is a picture taken of one of our control climate rooms, growth chambers. There appears we're growing a series of plants under some fairly high light intensity. The purpose of these control climate rooms is to exactly control all environmental aspects, relative humidity, air temperature, air flow, various gas concentrations, soil temperatures, light intensity, so that we can find out with a reasonable degree of assurance and reproducibility, what impact the chemical is having on the plant under certain conditions; or conversely, to find out what impact the plant is having on the chemical. And these growth chambers are extremely expensive to maintain. They're under a great deal of automation, automatic controls, adjustment recorders and so forth.

Q. Do they relate in any way to your metabolism [173] studies?

A. These are one of the key components in determining the fate of chemicals in soils and in plants, which is a key part of the metabolism studies.

The COURT: Pardon me, artificial light is comparable to sunlight?

A. No, sir.

The Court: I was just wondering about the possibility of photosynthesis?

A. Well, you're right. And most of the early works on growth chambers were not good work, because they did not design the proper lights that would give the equivalent of sunlight. And since that point in time they have gone back and you buy a specially designed bulb that gives you the quality of light you want. It's an art in terms of being able to design your—get the light intensity

you want and not get too much heat generated, and get the quality of light you want.

The COURT: Go ahead.

By Mr. HEINEMAN:

Q. Now in discussing generally the metabolism, residue and environmental chemistry aspect, let me hand you what has been marked for identification purposes as plaintiff's Exhibit No. 6, and ask you if you would examine that and identify it for the record, please.

A. This is a rather detailed, one-page sheet [174] showing what takes place from discovery to sales of a pesticide target, starting at the top, identifying the target. You might point out that although you identify Johnson grass as a target, for instance, you always ask yourself the question as the years go by, is it still a viable target. With Johnson grass the answer is yes. With some other weeds we say no. We will not screen against those weeds anymore, they are not commercially important. So the reason it's a dotted line, that's an open-ended assignment.

On synthesis, in the second one, obviously when we discover the chemical, the bar at the end of the solid line says we have discovered it. But synthesis also continues as you look for a better candidate. In the biological evaluation for patent application, once again you file for the patent with a certain amount of data, as I indicated on the earlier chart. But once again, you continue your biological evaluations even though you have filed for a patent application.

The research field plots show no bar and are openended because we continue research field plots with products until they're dropped from commercialization. There is never an end to putting our research field plots for any product that you sell.

Q. Let me ask you, tell the Court for the record [175] how this document came to be prepared and what it represents.

A. Well, this represents the various components, if you will, with the exception of the patent application. But

even the biological evaluation of the patent application, all of these are component parts of the registration package down through No. 10, that is submitted to EPA for label approval.

Q. And how was this document prepared?

A. This was done by working with the various people who have these responsibilities.

Q. And was it done-

The COURT: Well, now, just a minute. I'm drawing a red line under toxicology.

A. Yes, sir.

The COURT: Is it your testimony that everything above that line goes to EPA in connection with an application for registration?

A. Well, No. 6, the commercial decision, really is not data; but it's a checkpoint that is made. So you can scratch that. But everything, 2 through 10, with the exception of the commercialization decision, is a part of the registration package.

The COURT: Anything below that line?

A. Some part of the process chemistry, No. 13. [176] And of course we submit a label for EPA approval, No. 13. There's two 13's on there.

The Court: Two 14's.

A. Yes, two 13's and 14's. Anyway, both 13's are submitted. In other words, we submit a label which EPA accepts or rejects or asks that we modify.

The COURT: Let me ask one question which I'm sure everybody will say is facetious. But due to the efforts of the manufacturers of herbicides, have these efforts ever made certain weeds an endangered species?

A. No, sir, not to my knowledge. I guess that's one of the bright spots that you can say about the field of herbicides. We used to think that we would eradicate some weeds; but as we have gotten smarter over the years we found out that weeds are going to be with us as long as we have agriculture.

The COURT: Go ahead.

By Mr. HEINEMAN:

Q. Now is Exhibit 6 prepared under your direction, Dr. Carpenter?

A. Yes.

Q. And would you tell us across the top there it shows years. Now what—

A. Well, if you look-you really have under synthesis. you show that as actually having the compound made at minus the first year with zero year starting-going [177] in that last year before you reach the first biological evaluation. Anytime after that zero year that compound has looked promising enough that you're going to work with it. In other words, you have said this is a candidate for commercialization as opposed to item 6, which is your commercialization decision. That's when you really decided that you will commit all of the resources necessary. and that you have decided that is a commercial candidate or is a commercial product, until you've shown otherwise. Up until year three it's a candidate for commercialization; but you haven't committed the resources that are committed. If you will note after item 6, metabolism and environmental chemistry, residue and toxicology starts in earnest at that point in time.

Q. And those are the areas which you're preparing for the actual registration of a product?

A. That's correct.

Q. Now prior to that time the biological evaluation, the research field tests and the product development field tests, are the results of these tests also submitted to EPA?

A. Yes, they are.

Q. Now you touched briefly yesterday on the subject of metabolism. And the metabolism, would you explain for the record in general terms what the metabolism [178] tests accomplish?

A. In general, the metabolism tests are the beginning of those studies in terms of what we're trying to accomplish. That will show what happens to the chemical in the environment, in water, what impact it will—how it's broken down in the plant, how it's broken down in the soils, and indeed, how it's broken down in the animals in the event that they ingest it. In other words, it's the fate of the chemical.

The Court: Counsel, there's been no objection but I recall with some clarity his testimony yesterday. And I think this may be repetitious. I think he's going back over the same track on what happens; because he went into that in some detail yesterday.

Mr. HEINEMAN: All right, sir.

By Mr. HEINEMAN:

Q. Let me have you identify some of these photographs, Dr. Carpenter. First of all, would you look at what's been marked as plaintiff's Exhibit No. 4-E and identify that for the record, please?

A. In order to handle the massive amount of data in all phases of our toxicology, our synthesis, our screening, our metabolism, our residue, all of our programs, we now have put on a data system, a computer system if you will. And we now have extremely large sophisticated computer programs to enable us to handle recall, utilize [179] this massive amount of data generated by all aspects of the program on the chart we have discussed earlier. And this is the computer room, our central computer room for agriculture.

Q. This is just for the Ag Products Company?

A. That's right.

Q. Now let me hand you what's been marked for identification purposes as plaintiff's Exhibit 4-R and ask you to examine that and identify it for the Court, please.

A. This is another one of our scientists. In this case, this man is working on analytical methodology detections of minute amounts of material. He could be doing this as part of the residue group, he could be doing it as part of the metabolism group. But at any rate, this is extremely sensitive, complex work.

Q. Let me hand you what has been marked for identification purposes as plaintiff's Exhibit No. 4-A and ask you to examine that and identify it for the record, please.

A. Over under the lighted chamber to the left, in the left-hand part of the picture there is a soybean plant sitting there. And the instruments that are shown in the center part of the picture are hooked in by various techniques to record the gas exchanges of the soybean leaf in a very sensitive manner and determine such things as evolution of the radioactive pesticides, if we were to find [180] radioactive materials, or to measure photosynthesis, the impact of the chemical on photosynthesis or some other scientific aspect.

Q. And a little more detailed photograph which is marked for identification purposes as 4-G. If you would examine that and identify it for the record, please.

A. This is a closeup of the plant that was shown in the previous photograph in which you have the soybean plant, and we use only one leaf of the plant for our measuring purposes. And the rest of the soybean plant, the leaf remains attached to the soybean plant while we're carrying out these very sensitive measures. It's a rather unique tool.

Q. And what is in the chamber there to the left? Is that where the leaf is located?

A. The leaf is in the chamber itself and isolated completely in an independent atmosphere. All of this data must be used in submission to EPA for the metabolism requirements for registration.

Q. Let me hand you what has been marked for identification purposes as plaintiff's Exhibit No. 4-H, and ask you to examine that and identify it for the record, please.

A. We frequently work with radioisotopes or labeled materials. This represents one of the instruments [181] that we use in determining the various levels of radioactivity in the various fractions that we're measuring.

Q. And if you would, please, examine what has been marked as plaintiff's Exhibit 4-D and identify that for the record, please.

A. We're growing corn here in nutrient culture, probably these will go into our growth—control climate room, or growth chambers that will be used for either metabolism, residue or some purpose. And these—each pot is monitored by a number of devices to make sure concentration, salinity, oxidation and—oxygenization and all these other factors are—so that the plants are grown identical.

Q. To maintain an identical growth situation for each plant?

A. That's right, and reproducible from one experiment to another.

Q. Let me hand you what has been marked as Exhibit 4-P, and ask you to examine that and identify it for the Court, please.

A. This is a bank of chromatographs that we use to determine various fractions of the pesticide in the various fractions of the plant. In other words, this is part of the residue analysis. I might add that our [182] Director of Environmental Chemistry who also has responsibility for the residue work has pointed out to the new product committee meetings on occasion that the equipment used for analytical purposes by and large is getting outdated every three to five years. The methodology is changing so rapidly that the equipment that we're using has a certain level of efficiency, or a certain level of precision or detection. And these are rapidly being replaced by better equipment. And if you're going to have the up-to-date equipment, be at the leading edge of technology, then you must be continually updating your equipment, if you're going to have the best science and best equipment available.

Q. Let me hand you next what's been marked for identification as plaintiff's Exhibit 4-B and ask you to examine that and identify it for the Court, please.

A. This is a picture of a person working in our toxicology laboratories which we call our environmental health labs, where they're examining a slide of animal tissue from one of our toxicology studies, to determine the impact, if any, of the chemical on the animal.

Q. And if you would examine for me, please, Exhibit 4-F and describe that for the Court, please.

A. This is a battery of cages, in this case I believe those are white rats. We use rats as one of the [183] more frequent animals in toxicology, and particularly for the long-term chronic studies that go on for thirty months. As they test animals this is one of the batteries we use.

Q. And if you would examine, please, Exhibit 4-O and identify that for the Court, please.

A. This lady is preparing a tissue slide from one of the toxicology studies which would then be examined, if you will, by the person that we looked at earlier that was examining one of these slides. In a single rat study now we are up to, depending upon the type of study, between ten and twenty-five thousand slides per study when you conduct toxicology studies.

The COURT: In other words, what this lady here is doing is mounting the slides for later inspection?

A. Yes, sir, exactly.

By Mr. HEINEMAN:

Q. Let me hand you, if I may, Exhibit 4-I and have you examine that, and identify it for the Court, please.

A. This is another computer room. And this is where we're computerizing—putting our toxicology data in on the computer similar to that that we—that much larger room that handled all of our other data out at our research labs. And also it has an information storage and retrieval system whereby we can call up various toxicology studies and [184] information on various products.

Q. And is your environmental health laboratory located here at St. Louis as well?

A. Yes, it's not far from Barnes Hospital, in that area.

Q. Now, Dr. Carpenter, would you tell the Court briefly how does the EPA, to your knowledge, go about examining Monsanto's data for the purpose of granting or rejecting a registration?

Ms. MAYER: I object, your Honor. I don't think there's been any—the witness can speak to how EPA analyzes Monsanto's data.

The Court: Well, if he knows he may testify. If he don't know he can say so.

A. The registration group in Monsanto that handles our petitions and submissions to EPA reported to me for several years. The registration manager, Dr. Serti, reports it directly to me. The correspondence that the registration group and our Washington office had both to and from EPA came across my desk. The visits that our people had with EPA were discussed by these people with me. To that end, when a petition is received—

Ms. MAYER: Your Honor, I think that he can certainly testify about Monsanto's experience. But I think the question was how does EPA handle what Monsanto——

[185] The Court: Well, his answers are being restricted to how EPA handles their affairs with Monsanto.

A. Yes, sir.

Mr. HEINEMAN: That's the intent.

The COURT: And I wonder in passing—and this is certainly no inference pro or con on EPA—but I'm wondering if this litigation which started in early '79 has had any effect on the failure to register Machete?

A. No. sir.

The Court: All right. Well, go ahead. I wanted to get that out of the way.

A. We got all sorts of arguments but that is not one of them.

The COURT: You may testify as to—and this may violate the hearsay rule—but you may testify as to what you observed from documentation received from your people and your Washington folks, together with their professional comments to you concerning that. A. I might say that I have also called on EPA in the EPA registration group, including Mr. Taylor of EPA who is responsible for herbicide registrations in Monsanto products specifically. I have called on him in his office in EPA several times to discuss specific registration issues. I have called on Ed Johnson who heads up all—who heads up the Office of Pesticides for all of EPA. And I have called [186] on him in his office and had discussions with him.

Usually a petition for registration, or a new use for a registration is received by EPA and they have groups that handle various aspects of the petition. For instance, they would have those people that are assigned to look at the metabolism area, those people that would be assigned to look at the toxicology area, and so forth. So that the appropriate people or sections of EPA would look at the various sections, and they would review it and send it back to some central place with appropriate comments.

The COURT: Now supposen I come in with a me-too application. Who handles that? The same people or if you know? Well, wait a minute, you never filed a me-too, have you? I withdraw the question.

A. We haven't filed a me-too, nor has a me-too been granted for our products.

The COURT: All right. Go ahead.

By Mr. HEINEMAN:

Q. Well, then, Dr. Carpenter, does the EPA, to your knowledge, sir, examine and review the data that you submit on a new product when you submit it for registration?

A. Yes.

Q. All right. Do you have an opinion, sir, as to whether or not that that can be thoroughly evaluated by the EPA without necessity of public disclosure?

[187] A. Yes, it can be.

The Court: He has an opinion, and the answer is yes. By Mr. HEINEMAN:

Q. To your knowledge, sir, does EPA have any other sources available to it in terms of evaluation of data, other than public disclosure?

A. There are procedures that have involved our products called the RPAR process. And this stands for rebutable presumption. And this is when there is a currently registered product and some new data would come up that would cause EPA to have concern about that product; at that point in time the company must then go back and rebut the presumption that it should be cancelled or some change should be made. The EPA has a group of scientists called the Scientific Advisory Panel which consists of outside scientists who are experts in certain fields including toxicology, medicine, metabolism, physiology, what have you. And the data is presented to them both by EPA and by the company, or the owner of the registration. And the Scientific Advisory Panel reviews that data and makes recommendations to EPA for actions to be taken. The EPA may or may not choose to follow any or all of the recommendations of the advisory panel. there is a broader scientific advisory board for all of EPA, and they have various subsections for other issues.

[188] Q. In your opinion, sir, does the public disclosure called for by the 1978 amendments to FIFRA add anything to this decisionmaking process?

A. No, it does not.

Q. Do you have an opinion, sir, as to the ability of the public to understand and comprehend the data that Monsanto has submitted in support of the registration for example of Roundup?

A. The data contained on that cart over there [189] represents the data that has been submitted for Roundup. The data is extremely complex, and in fact, very few scientists could follow with any detail and interpret that data. The vast majority of the pubic, including me, cannot

follow some of that data. And I regard myself as very skilled in this.

By Mr. HEINEMAN: [190]

Q. Dr. Carpenter, does the label that Monsanto submits to the EPA for approval contain safety precautions for handling and use of the product?

A. Yes, it does.

Q. Does the data which is submitted in support of the registration in any way explain or make more clear to the user those safety precautions that are listed on the label?

A. No, they do not.

Q. Do you have an opinion, sir, as to whether or not there would be benefit to be derived from replicative studies in support of registration of the same chemicals?

A. There would be incremental benefits to be gained. We replicate our own efficacy data dozens of times to insure that we are writing the best label for consistency. Since manufacturing processes can vary as to how the active ingredient is made, that certain byproducts of the manufacturing process themselves can vary in terms of amount, the presence of them, the ratio of them, this [191] can affect the toxicology properties of the chemical and therefore could affect the type of warning that would be needed on the label. There are a number of ways that repetitive testing could be useful.

The Court: Well, getting down to the bare bones-hand me that one little four-page document that somebody referred to yesterday. And I'm not going to mark it as an exhibit, but I just want to look at it. Yes, that's the one.

This is the secret of secrets, is it?

Mr. Heineman: Yes, sir.

The Court: All right, Now the Court has in its hand the document-and I'm not going to mark it as an exhibit or-that's up to you folks. This document says volume 2 of 19, section A chemistry, section B use directions. This is that part that is not disclosable?

A. Yes, sir.

[199] By Mr. Heineman:

Q. Dr. Carpenter, what is it [200] that is disclosed, sir, by—let's assume in connection with the Roundup data, the data that's been submitted to EPA in support of the Roundup registration, what is it in that data which the 1978 amendments to FIFRA contemplate being disclosed?

A. Well, the items that I checked off that were on the chart earlier, efficacy, metabolism, environmental impact, toxicology, in fact, once again, everything in the petition except the few pages of formulation and manufacturing process.

[201] By Mr. Heineman:

Q. Now, Dr. Carpenter, previously you had reference to one book, a very thin book which was volume 2 of all of the data that was on the sled over here and was identified by you and a photograph of that data, which was Exhibit 7-A and B.

A. Yes, sir.

Q. Now in connection with that one book let me hand you what has been previously marked as plaintiff's Exhibit No. 39, and ask you to examine that and compare it with a portion of that book which you previously discussed.

[202] A. Yes. These are the procedures—or this is the formulation data which is to be held confidential and is excluded from consideration under 3(C) and 10(D), these two pages.

By Mr. HEINEMAN:

Q. Okay. Now Exhibit 39 is a Xerox copy of the first two pages of section A of volume 2 of 19 of the information to support the establishment of permanent tolerances and label registration for the use of Roundup as a preplant herbicide on corn, soybeans, wheat and other small grains, dated July 12, 1974; is that correct?

A. Yes, sir.

[216] By Mr. Heineman:

Q. Dr. Carpenter, what is it that is contained in Exhibit 39?

A. It has the name of the chemical and then the structural formula of the chemical, a brief listing of the physical and chemical properties, and then the composition of the product itself which is to be sold to the public, and then a brief paragraph briefly describing how we make the active ingredient.

[217] Q. Is that the latter labeled manufacturing process?

A. Yes, it is.

Q. And what is contained on page 1 is what Monsanto refers to as the confidential formula?

A. Yes, it is.

[218] By Mr. Heineman:

Q. Now, Dr. Carpenter, let me hand you what has been marked for identification purposes as plaintiff's Exhibit No. 14, and let me ask you to examine that and identify it for the Court.

A. This is a letter to Monsanto from the Environmental Protection Agency. They sent it our Washington office which—and then our Washington office refers it to the proper person within Monsanto. This is a request or a letter from EPA stating that they have received a freedom of information request from Ciba-Geigy Corporation asking for our data on—and they give a registration number 524-EUP-56. 524 stands for the Monsanto registration. Any product that EPA gives a label to Monsanto starts with the number 524. EUP stands for experimental use permit, indicating that it's used under section 5 of the Act. And it's just that experimental use. And there's certain things we have to do to comply [219] with that. And 56 just has a number of definitions. But 524-EUP-56 has to do with Roundup. That is an experimental use permit

for Roundup, one of the documents for Roundup that we have submitted to the Agency. And this says that EPA will determine if the document is entitled to confidential treatment.

[220] By Mr. Heineman:

Now, Dr. Carpenter, let me hand you what has been marked for identification purposes as plaintiff's Exhibit No. 13 and ask you to examine that and indentify it for the record, please.

A. This is a pesticide catalog of a company called Aceto in which they list the various pesticides which they say that they will supply, they will sell to customers. And it is broken out.

The Court: Well, they're a jobber I take it instead of a manufacturer; is that correct, or not?

A. Well, we refer to them quite frequently as one of the me-tooers. They buy their technical material from a wide range of sources including foreign manufacturers, and then offer it in competition. They are an example of the type of people that will come in for a request of use of your data to register their product. They carry—this company has no basic research in screening. I have never seen in my twenty something years in the pesticide field, I have seen no evidence of a techical effort of a toxicology [221] effort, of an environmental impact effort on the part of this organization. They merely are jobbers, is one way of expressing it.

By. Mr. HEINEMAN:

Q. I note, sir, that on the second page of that exhibit where they list herbicides, they list the Aceto brand name on the left and then the competitior's brand name on the right?

A. Yes, sir.

Q. Has Monsanto, to your knowledge, yet appeared in an Aceto pesticide catalog?

A. Yes. In the early years they did have either Ramrod or Lasso listed as one of the things offered for sale in the

U.S. And upon questioning by Monsanto they acknowledged they did not. And in this particular issue the Monsanto products were not listed.

Q. Were those products offered by Aceto in that catalog at a time when they were under patent in the United States?

A. Yes, they were.

Q. But, they have been omitted from the 1980 catalog?

A. They're not listed in this 1980 catalog.

[222]

## CROSS-EXAMINATION

By Ms. MAYER:

A. I think what I said was that we apply for [223] patents for a substantially larger number of chemicals than we commercialize. However, we probably apply for only one out of ten to one out of a hundred of the chemicals that we made. In other woods, we do not apply for patents for every chemical we make, only for certain ones.

Q. But for chemicals that you have——

A. Applied for.

Q. [continuing]: —applied for a patent on, what is the number of years, if you can estimate, what is the number or years between application and issuance of the patent?

A. We have gotten chemicals in as short a time as a year. In some cases we have—it has taken six years.

Q. Okay. Fine. Now I'd like to focus on two chemicals, two herbicides that Monsanto has discovered and commercialized. The first one we focus on is Lasso. Is it true that Lasso was registered with the EPA in 1969?

A. It was registered for the first use in 1969. I think we actually got our first registration with USDA—EPA did not exist at that time—we got our first registration in December of '68, I believe, but it was for the '69 season.

Q. Fine. Is it true that Lasso was patented also in 1969?

- A. No, it was patented later than that, I think [224] I mentioned that in my testimony. But I think we received our patent on that in 1972.
- Q. So that you were able to sell Lasso for, let's say two years, approximately two years before actually receiving your patent?
  - A. That's correct.
- Q. And then you had another seventeen years of patent protection after you received the patent?
- A. Yes, we have seventeen years after we receive the patent.
  - Q. For a total of nineteen years after registration?
- A. We received the patent—we had patent protection for seventeen years. We will have patent protection in the nineteenth year of our sales.
- Q. Fine. Have you recovered all of your costs incurred in developing Lasso?
  - A. Yes.
- Q. Do you know at what point you recovered all those costs?
  - A. Well--
  - Q. If you know.
- A. The question is have we recovered all of our costs. We continue to apply additional costs to Lasso. If you look—if you are referring to the original [225] cost of registration and of the investment that was needed to get us to our first year of sales, we recovered those at approximately 1973 or '74. But since that time we have invested, in terms on plant, equipment, and other expense resources, we have continued to expand our plant and there are probably a significant part of our capital now for Lasso which have not been recovered as of yet.
- Q. Okay. If I might, you had drawn a graph on one of these exhibits. I believe it was Exhibit No. 38?
  - A. Yes.
  - Q. Yes.
- A. And if you are asking me have we recovered this—

Q. Yes.

A. Yes, we have recovered that.

Q. And was that done in '73 or '74?

A. Approximately '73 or '74.

Q. All right. Okay. Now concerning Roundup, was that registered with EPA in about 1976?

A. Our first crop use was registered in 1976 for use in crops. Our first commercial use involving an EPA registration was for non-crop use. And I believe that was in either late '74, but in time for 1975 sales.

Q. And when was Roundup patented?

A. It was '74, '75 to the best of my knowledge.

[226] Q. So it was within a year or two before receiving your first crop registration?

A. It was about the same time or a year plus or minus either way.

Q. And that patent will run into the 1990's; isn't that correct?

A. Seventeen in '75-'92.

Q. Okay. Now you testified that that is one of your most profitable herbicides; isn't that correct?

A. Yes.

Q. Have you recovered all of your costs on Roundup in that same meaning as—

A. In comparison to the same situation for Lasso in terms of initial cost pertaining to registration and initial sales, yes.

[240] Q. Going back to this plaintiff's Exhibit No. 5, did you take into account any tax consequences or depreciation or deductions when you were figuring your cost figures?

A. No, we looked at cost.

Q. So you did not?

A. Expenses.

Q. Okay. And you did not incorporate any tax advantages or tax consequences of your expenditures?

A. No, we did not.

- Q. And it's a fact that generally your captial expenditures are depreciated on your income tax return; is that correct?
  - A. Yes.
- Q. And your expenses are deducted on your income tax returns?
  - A. To the extent there's a profit, yes.
- Q. Okay. Can you give me examples of what kind of expenses you would deduct?
- A. All research expenditures or valid cost figures of doing business.
  - Q. How about salaries?
  - A. That's part of the research effort, yes.
- [241] Q. What kind of things are capital expenditures that you would depreciate? Would all of this equipment that you have testified about and that we have seen in some of these pictures, would that kind of equipment be depreciated on your tax returns, if you know?
- A. We use as a point of departure, as a general rule if it hasn't changed in the last year or two, a little less than a thousand dollars as to whether we expense an item and deduct the total amount as an expense of doing business, or whether we capitalize it. Now by and large most of these items of equipment that are in the photographs were far greater than a thousand dollars. And they would be capitalized, in other words written off over a number of years as opposed to being written off in a single year's expense.
- Q. You are aware that under section 3(c)(1)(D) of of the act other companies don't have actual physical access to your data; is that correct?
  - A. Yes.

[250] Q. Okay. During your direct testimony I think you testified that one of the possible results of disclosure under section 10 is that a company could use your data in a foreign country to get a foreign registration. Was that your testimony?

A. Yes.

Q. Are you aware that under section 10 registration information is not disclosable to companies that do business in foreign countries?

A. The letter that we turned in in Exhibit 39—I beg your pardon—plaintiff's Exhibit No. 14, was a request for

data from Ciba Geigy.

Q. Was that disclosed, was any information disclosed to Ciba Geigy?

A. If we had not acted on our own to prevent it it would have been disclosed. The Agency was prepared to give it to them if we had done it regardless of whether it was multinational or not.

Q. My question was, was any information disclosed as a result of the Ciba-Geigy request?

A. No.

[255] Q. In your direct testimony you also testified, I think, that there are about eight to ten companies in the United States with research and development capabilities that are on par with Monsanto's; do you recall that?

A. Yes.

Q. Can you name those companies for me? And let me combine two questions because I think it would be easier. And when you name them, can you indicate whether or not those companies operate in foreign countries?

A. All of the companies that I will name do operate in foreign countries, okay. Dow, du Pont, American Cyan,

Stauffer, Union Carbide, Eli Lilly, Velsicol.

Q. I think that's seven. If you can't recall any others, that's fine.

A. Well, that's the flavor.

[256] Q. So all of these are multinational corporations?

A. Yes.

Q. And data may not be disclosed to them under the operation of section 10; isn't that correct?

A. According to the statute.

[263] A. Okay. In order to have a final end product you would have to start with the technical pesticide, which I referred to earlier. You would have to develop—if you were going to make—if you were going to—you, company X, were going to start with your own—make your own, and were not going to purchase it from outside this country and you were going to rely upon your own manufacturing sources, then you would have to obviously develop a manufacturing process. And that would give you the technical pesticides to work with. You then could take the technical pesticide and would from there, you would develop your own confidential [264] formulation.

Q. Fine.

A. Is that your?

Q. Yes, that's fine. And I think you testified that, depending upon the actual formulation that you arrived at, there can be a big difference in the final product. You can take an active ingredient and formulate it in different ways and your results may vary widely; isn't that correct?

A. Yes.

Q. So that the actual formulation is very important and can make a big difference in whether or not a chemical or—I'm sorry—a final end product, herbicide, will be marketable; isn't that correct?

A. That's correct.

Q. I think you also testified that the manufacturing processes are also very important in whether or not your herbicide makes it on the market; isn't that correct?

A. Yes.

Q. And that it's important that you get your factory going and that you figure out how you're going to comply with all other kinds of laws, including other environmental laws like the Clean Air Act and the Clean Water Act; isn't that correct?

[265] A. That's correct.

- Q. And again, this information is not disclosable within the meaning of the statute; isn't that correct, under the terms of section 10?
  - A. That's correct.
- Q. And, of course, a company would still have to come up with its own marketing strategy; determine, you know, what markets it was going to try to penetrate, how much advertising it was going to do, who it was going to try to target its sales to. A company would have to come up on all that on its own too; isn't that correct?

A. It would have to develop its own marketing procedures.

- [273] Q. Isn't it a fact that at times Monsanto itself publishes procedures for and results of its various tests?
  - A. Yes.
- Q. And that Monsanto sometimes publishes efficacy data, methodology data, analytical data and environmental data?
  - A. Run those by me again?
  - Q. Efficacy data, methodology data?
  - A. Yes.
  - Q. Analytical data?
  - A. Yes.
  - Q. Environmental data?
  - A. Yes.

[275] Q. Do you actually provide the data to users?

A. Usually. In fact, I can't think of an exception. We usually provide them with summaries of the data. The academic data, the one generated by the universities is not our property. That's the property of the university. And usually the extension people at the university. And usually the extension people at the university also present that data. But even there, although it's available usually the university people present summaries. But that data which has both our product and our competi-

tors product in the same test is not our data. And that's usually made public by the USDA and academic people.

[276] The COURT: And, of course, there's a certain amount of salesmanship in this business when you get out in the farmer's town. And I appreciate the question going to what information, data or whatever you want to call it is furnished voluntarily by Monsanto over and above, or in addition to what is on the label.

A. Your Honor, the point is that the data we choose to supply to the public, or to our customer, is that data that we choose to do on our own by way of all of the impact it will have on Monsanto, the need to know and so forth. And the publication of analytical data or environmental data, we see that it provides a number of useful purposes, things that we decided that represent—where the advantages outweigh the disadvantages, to build a scientific reputation of our own scientists, to encourage—[277] to get status for them. We also do it to demonstrate the effectiveness. Sometimes it's necessary in some of our foreign registrations where an article published in a competent scientific journal is useful to a foreign company over and above——

The Court: Does your competition do about the same thing?

A. Yes, sir.

The Court: Are you able to learn anything from what they do over and above labels as to what the product is?

A. We obtain a certain amount of information from doing that; and they—in turn we recognize we're giving up a certain amount of information. But once again, we have internally weighed the decision. Before we release such an article it has to be approved by our Director of Patents, our Director of Research, the Director of Development, and in some cases by our Managing Director. So that we are very deliberate and very methodical about how we decide to release the data.

The Court: In other words, what you're telling me is you play those cards pretty close to your vest; is that right?

A. Yes, sir, very deliberately, very judiciously, if I may use the word.

[279] Q. I asked you a question about whether Monsanto was able to use the data that it submits to EPA in developing new tests in trying to figure out what new chemicals to pursue, you know, in future research. Now there is nothing in section 3(c)(1)(D) or section 10 which precludes Monsanto or interferes with Monsanto's use of that data?

A. That's correct.

[280] By Ms. MAYER:

Q. Okay. One other question I'd like to clear up is, just before we broke I was asking you whether most of the techniques that Monsanto uses in its toxicology studies and its residue studies are known. And I meant to say whether they're known to other companies, but I may have said whether they're known to Monsanto. Are these—let me just reask the question, whether—isn't it [281] a fact that most of the techniques that Monsanto uses for residue detection, for toxicity tests, for fish and wildlife tests are known to other companies in the field?

A. No.

[313] Q. Isn't it a fact that if Monsanto is the only company on the market selling a certain herbicide, that it may then essentially price its herbicide by what the

market will bear?

A. Absolutely no. We do not have a single use of Roundup, or a single use of Lasso where we don't have two or more competitors. Even though it's not the same chemical we must price—first of all we like to price to value. You were asking me about how we determine price and what the market will bear. We like to get for our product what we think it's worth. But we're also faced

with a competitive situation. For instance, in Lasso and [314] soybeans, there's ten competitors out there that we must consider as to what our pricing situation is.

[326] Q. Since 1950 has Monsanto been committed to research and development of herbicides?

A. Yes.

Q. Since 1978 has Monsanto lessened that commitment to the research and development of herbicides?

A. No.

Q. Since 1978 has Monsanto submitted data to the Environmental Protection Agency in support of its registrations for its herbicides?

A. Yes, it has.

Q. So you continue to support data in spite of the fact that this statute is on the books?

A. We continue to submit it.

[338] By Ms. MAYER:

Q. Dr. Carpenter, before the break we were discussing the disclosure provisions of section 10 of FIFRA. Is it your primary concern with disclosure that through disclosure someone might be able to infer your confidential statement of formula and manufacturing processes from this information?

A. No.

Q. Okay. So you're not concerned with that?

A. Yes, I am concerned. You asked if that was my primary concern. I am concerned about it, but that is not my primary concern.

[350] Q. Okay. Fine. Is it fair to say that in order to determine whether a given pesticide is "safe for use" you would need to know all of this type of information?

A. Yes. When you refer to safe, you're referring to safe to the environment, safe to fish and wildlife, safe to humans, safe to the consumer, and so forth. And then all of the data together would be needed.

- Q. Fine. Are you aware that union groups that represent workers in chemical companies and also groups of farmers and people—farmers who can be exposed to these pesticides are interested in this type of information?

  [351] A. Yes.
- Q. Isn't it a fact that scientists outside of Monsanto can evaluate this data?
- A. Your question is are there scientists outside of Monsanto who have the capability of evaluating that data, then the answer is yes.
- Q. Are you aware that union groups and environmental groups can employ scientists capable of evaluating this data?
  - A. They can, yes.
- Q. Okay. And isn't it a fact that scientists at universities can evaluate this data?
  - A. Yes.
- Q. As a scientist if you wanted to evaluate any of the studies performed by Monsanto on, let's say Roundup, and determine whether that study was scientifically valid, wouldn't you want to examine that study itself?
  - A. Am I doing this as-
  - Q. As a scientist?
- A. Not as a person charged with doing it under the regulations?
  - Q. As a scientist?
  - A. As a scientist I would want to see the data.

[362]

## REDIRECT EXAMINATION

By Mr. HEINEMAN:

[363] Q. Dr. Carpenter, in response to questioning by the government you testified that the damages to Monsanto [364] were not quantifiable. I wonder if you would, for the record, say why they're not quantifiable?

A. Well, in addition to not being sure what data will eventually be released, the term—the commercial implications of either use or disclosure—we're talking about use in this case, I presume, or are we talking about disclosure?

Q. Well, disclosure was what I had in mind, primarily.

A. Well, there's no way of determining what might be the fate of that data in terms of once a person who is duly authorized to receive that, he's not a multinational, he could with that data, he could then decide to publish it in the Sierra Club news and/or distribute copies to many of his members. And perhaps as a Dow or a Du Pont man that's president of the local Sierra Club or a Ciba-Geigy man, perhaps he is a bonafide member of an environmental group, and a year later without any planning or forethought joins a multinational company or goes to work for Aceto Chemical Company. So that there's no way of telling what is going to be the fate of that data once it's disclosed. There's no way for the data to be, from a practical standpoint, being kept from the hands of those people that could utilize it in ways that we would not like to see it used. So it becomes impossible on disclosure [365] to determine what's going to happen.

Q. Is there any way to predict how many competitors of Monsanto, if any, would get access to it?

A. I have no way of knowing.

Q. And therefore, is there any way to predict what the market impact of such a disclosure would be?

A. No. there is not.

Q. Is there any way to predict what the impact of a use would be in terms of market penetration?

A. No. If under use of data, under section 3, if one competitor applies for our data and only goes for one market, or one crop, that has one impact. If it's Aceto, that's going to have one impact; but if Dow decides to go in with their massive resources, that's another impact. And if all of them think it's so interesting that we have fifty applying for it rather than one, or any number between one

and above, then it's impossible to predict the impact on the marketplace. And therefore, what had been originally from a Lasso standpoint a total Monsanto market.

Q. Is there any doubt in your mind that there would be an impact on the marketplace?

A. There's no doubt in my mind that there would be an impact, and the impact would be devastating.

Q. But you just can't put a number on it?

[366] A. I cannot put a number on it for those reasons.

Q. The Government inquired of you with respect to whether or not as a scientist you would want to see all of the data if someone wanted to register a substantially similar product to a Monsanto product?

A. Uh-huh.

Q. Would you tell the court why as a scientist you would want to see all the data?

A. Well, first of all, in the statement of formula, once again the statement of formula requires only that you list the inert ingredients. And certainly without any real analytical study of the components that are in the technical pesticide, with a very thorough analysis, in both-in the-both in the inert ingredients or the technical pesticide-well, not-the byproducts of the manufacturing process, if you manufacture something and you end up with ninety-four percent of the real pesticide and six percent of things that are not pesticide, that is your technical. That six percent can include dozens of chemicals, possiply. Now then when we do our toxicology studies we're doing something by the manufacturing process that we are using. So that when we test the technical pesticide for those four studies that were named earlier, the mouse chronic carcinogenic study, the rat chronic [367] carcinogenic study, the three generation study, and-let's seeand the reproduction study, teratology studies, we study the technical material. And by virture of studying that technical material, whatever impurities we have in our product we're also testing because they're fed to the rat. A product made by a different manufacturing process

that could still be ninety-four percent active and still have six percent of other things in it, would not necessarily and probably would not have the same active incredient—inert byproduct ingredients, things that we could not predict.

Now not only would this have impact on toxicology, but if you're starting out with a chemical that's-trying to make a chemical that's supposed to kill plants, and it indeed does, and the other six percent may or may not have some biological property, even though you're not claiming them as a pesticide, you're not claiming them as part of the pesticide, they're just listed as part of the six percent-they could have a deterimental effect on the performance of the product. They could have a deterimental effect on the crop safety. They might have a deterimental effect on the environment. You can say, well, gee, six percent doesn't do it and we don't have to worry about it. But by the same token when we find an impurity, as I indicated with roundup at less than one part per million, we [368] did substantial analytical studies, toxicology studies, environmental impact studies, and residue studies on that one incidental product, that compound that did occur in our Roundup technical. And certainly if we're looking at parts per million that's a far cry from six percent.

Q. What can be the impact upon Monsanto Company of a me-too product that does not have replicative testing done to identify this six percent byproduct?

A. When that me-too product is in the marketplace it is another form of—Lasso's scientific name is Alachlor. They have Alachlor 2 out there. When the farmer uses Alachlor, once he's bought it and put it on the ground, as far as he's concerned he has got Alachlor. A custom applicator might put it on for the farmer, and the custom applicator might in the course of his business be putting on both Lasso and Alachlor 2. If there is damage to any one of several things in terms of liability exposure, lack of control of weeds, damage to the crop, damage to the

applicator, environmental impact of toxicity damage, illegal residues in the crop, Monsanto can rest assured that it will be sucked into any liability case that might come about, and would suffer not only the impact of the liability but loss of its reputation.

Q. You were shown on cross-examination a document identified as pesticide analytical manual. What [369] sort of information is contained in that manual?

A. That provides information that enables the appropriate person with adequate facilities and skills to analyze in foods or feeds or elsewhere, for the presence of the pesticide and/or its metabolites.

Q. Is it current information?

A. It is adequate information in that it is useful for the purposes intended. But by and large, as I testified earlier, analytical procedures and equipment are rapidly being outdated every three to five years. It certainly would not be, in all probability, our latest technology. It would be technology that would be acceptable but would be outdated.

Q. Does the pesticide analytical manual which you examined today disclose the techniques and methodologies which Monsanto Company is regarding today as being proprietary and confidential?

A. No, it does not. We submitted that information voluntarily after we receive a registration for our product.

Q. That is the information for the analytical manual?

A. That's right.

Q. In terms of this publication issue and the things that are published, would you describe for the record how it is that Monsanto goes about deciding what [370] kind of publication to make, and when to publish it, and the extent to which you do make a publication.

A. Well, first of all, one determines if first on a scientific basis. For instance, the article dealing with glyphosate in soils, we wanted to publish this to get the results and the techniques even, out into the literature. There are a number of academic scientists who are interested in this

sort of thing who are doing work on that, and it was useful information but information that was something like three to four years old. So in determination of how we do this, as I mentioned earlier, our Director of Patents, our Director of Research, our Director of Development and in some cases our Company Counsel, review this from several standpoints, what risks or disadvantage do we suffer if any in doing this, what are the reasons for doing this, and what advantages accrue. And on that we make a basis of doing it. In passing, that which we publish in the referred journals is not the same report that we submit to EPA. It is still a condensation and represents less than one percent of the data that we have submitted to EPA.

Q. When you deal with an outside laboratory to prepare data for Monsanto to submit to the EPA, generally under what terms is that relationship conducted?

A. Well, there are two key terms. First of all they do it according to our specifications. And we approve [371] the specifications. But secondly, they sign a confidentiality agreement with us for treatment of the data.

[374]

## DEFENDANT'S CASE

HERBERT HARRISON was called as a witness, and being first duly sworn to tell the truth, the whole truth and nothing but the truth, testified as follows:

[467] By Ms. MULKEY:

Q. Okay. Mr. Harrison, based on your experience in the registration of pesticides, would you describe for us the changes over the years in the amount and type of data that have been submitted to the agency by pesticide registrants?

A. Yes. Your Honor, as you may well know, in 1947 the first FIFRA was promulgated, put into effect. And since

that time a lot of changes have taken place in both understanding of pesticides and their problems and the Act itself.

Originally the Act, as I understand it, was promulgated more for efficacy then for anything else. Farmers wanted to make sure that the products worked. So that the early submissions were heavy enough in efficacy and light in health related data. As time went on it wasn't too long after that I guess until Rachel Carson wrote her [468] book on Silent Spring. So the Act changed from time to time, changed rather significantly in '64 to ask for more data of a public health type or environmental type. In '72 it was increased significantly. But between '64 and '72 there were more and more pieces of data required by the agency.

I looked at the Monsanto submission of data in what we call our level 2 catalog. The oldest volume of data that I show for Monsanto in that catalog was submitted in 1948. And there were a couple of volumes submitted in 1950, and then they started to grow from that time. But if you go from the first submission in '48 to when the interim policy statements were issued in '73, there was essentially between one and a half to two volumes submitted per month. If you look at the data submitted between '73. November of '73 and October of '78 when the law again was changed at that point and the new provisions put into effect, then Monsanto submitted on the average of six point five volumes per month. So we go from one up to six and a half. And then from that time up until this last July which is the last report we have from that particular catalog, they submit roughly twelve volumes of data per month. So you go from one, essentially one and a half up to six and a half up to twelve.

So as you can see, the data requirements have [469] significantly increased; and particularly increased when you understand, your Honor, that those early data were in heavy part efficacy data. They were no longer from '78 requiring efficacy data, so that's very little. So we shifted

from efficacy data to public health and environmental data very heavily.

[474] By Ms. MULKEY:

Q. Do you understand, Mr. Harrison, my question is designed to solicit from you a [475] description of the practice with respect to me-toos?

A. Yes. The way registration process was accomplished prior to my time as becoming the branch chief of the ecological registration branch, was that again a program specialist, which I was one, would work with a particular discipline such as the fungicide group, rodenticide group, and so on. We would received applications for any fungicide or rodenticide in the case in which I was involved. and if there are other people doing the herbicides-and of course at one point I did herbicides for a period of timeand we would make sure that the reviewers who needed to look at the label and the application would look at those and make whatever statement they had to make about the label and application and so forth. Whether they needed data, whether they needed more data, whether they needed data at all, whether they needed to have the label changed to take care of use of the product or whatever. So in a graphic way, your Honor, what would happen is that I would take from my office a registration file and give it to one of the reviewers who would at that point look upon information he had at his disposal, which was ususally a catalog of sorts. It would either be kept in a notebook or in a file catalog or what have you, just a card catalog. And he would look to see the information contained on that card as to what had previously been registered by the agency [476] for that active ingredient. He would look at the uses that had been registered. He would look at the percentages of the active ingredients in those products that had been registered, and would make the determination whether the me-too in fact was using the same percentage, had the same usage. And if so,

would simply say he was happy with what he had seen, he needed no further information, and pass it along.

That would happen with the safety people. That would happen with the efficacy people, with the environmental people and so forth, the chemists. And that's the way we manage to get so many applications done very quickly. Again, when I first came on with USDA, we did about fifty to seventy applications a day. That is, we had the reviews done, we wrote the letters, proofed the letters and mailed them out and so forth. And that particular aspect has probably fallen considerably over the years because of the more complicated processes that we now go through. But even before I had arrived I think there were between maybe sixty and a hundred per day. Because they were moving things through very, very quickly without looking at much information.

So that the processes that took place at this particular time require very little data review on the part of our reviewers. They just use the card catalog they [477] had. And in fact, at that time, USDA was putting out a document called the EPA compendium of registered uses where they would have in this particular compendium a listing of the chemicals, the various crops we had registered, the dosage rates, the preharvest interval, various limitations for the product use and so forth. And quite often our reviewers would use that particular document to review whether or not this was consistent with previously registered product. And very seldom did we look at data. Only where there was a new use or new chemical involved did we go back and look at efficacy data or chemistry data or toxicology data and so forth.

Q. Let me posit a hypothetical.

A. Yes.

Q. Let us suppose that USDA had previously registered an active ingredient for a product that Monsanto got a label on. And that another company submitted a registration to the agency for a chemical which contained that active ingredient. And let us suppose that their submittal contained the following information: A label which looked exactly like Monsanto's label except that they changed the name of the company and the trademark of the product; a confidential statement of formula; and a request that the new label be approved. Would you describe the manner in which you would have handled such an [478] application?

Mr. Heineman: Your Honor, may I object to the form of the hypothetical question in terms of time?

The COURT: Well, of course, the Congressional Rules of Evidence has pretty well ruled against your position. You may cross-examine. Go ahead. Overruled.

By Ms. MULKEY:

Q. I think it would be helpful perhaps if we established this as—let's pick the year 1968.

A. To the best of my ability to recall, what would happen is, the application would come to my office and I would determine which ones of the reviewers, if not all, would have to look at this particular application. And I would carry it to those reviewers for their review. Now the reviewers would, in this particular hypothetical example, would have originally registered the Monsanto product. And in that registration process they would have captured the information about the use directions, about the dosage rates and so forth. The safety people would have gotten off the information about what the toxicity categories were that would show on the label, such as whether it was dangerous or less dangerous or what have you. And the fish and wildlife people would have captured the kind of information about what kinds of labeling would have to appear for the fish and wildlife precautions on the label. [479] And when the second or subsequent application would come in, the me-too, they would go through their file until they came to that particular item, and see if the percentages were the same, uses were the same. And if the label essentially carried those same precautions, use directions and so forth, they would simply give it an okay and send it forward. And that would go through the whole process in that manner and then be returned to myself. I would write the letter indicating that it could be registered and would immediately proceed to register it from that point.

Q. Okay. Would you—do you have in mind my hypothetical?

A. Yes.

Q. Would you take the same hypothetical except let's assume that the second application, the other company did not include a confidential statement of formula. How would you handle that kind of application?

A. We would obviously go back and ask the me-too applicant submitter, or the applicant to submit a statement of confidential formula. Now quite often what happened in those days was that they were buying a product from some other company, they'd be getting it off the shelf and buying it from Monsanto. But at that time they would have to go back to Monsanto and ask Monsanto to submit in their behalf their confidential formula for the product that they may be [480] buying off the shelf rather than going and buying it directly from Monsanto. Or if they bought it directly from Monsanto, Monsanto would have to support that company's registration basically with the confidential statement of formula so that we could know what was in the original product. And then we would have to know from the me-too if it was simply all of Monsanto's product or he was adding some carriers or what have you. But of course if the percentages were the same it probably simply would be are repackaging of Monsanto's product.

Q. Okay. Now so that I'm absolutely—so that we're absolutely clear on what you've just described, would you require that the me-tooer secure any permissions from Monsanto or anyone else, so long as the me-too's application package did include a confidential statement of formula?

A. Yes. Again, you see in order to make a determination on the appropriateness of the application we would have to know what was in the product. Now in the case of this me-tooer, if he was using a Monsanto productlet's say it was a fifty percent emulsifiable concentrate, which meant that the active ingredient was at the level of fifty percent of the total product that they were buying from Monsanto-the purchaser, that is the me-too manufacturer, would not know what the other fifty percent was because that's inert ingredients and kept [481] confidential. So he would have to go to Monsanto and ask Monsanto to give him permission for the agency to either look in Monsanto's files for the original confidential formula, or in many cases would have Monsanto send that formula to us saying you can use this formula to support our registration. So that at that point we would know totally what was in the me-too formula. We would know what Monsanto had first put into their formula and then subsequently what the me-tooer had put or added to the Monsanto formula to make their product.

Q. And keeping in mind my hypothetical, did you in conducting your responsibilities at that time require the me-too applicant to secure any permissions from Monsanto in connection with anything other than the confidential statement of formula?

A. No, we did not.

Q. When you first went to USDA, that was when, in 1967?

A. June of 1967, I believe.

Q. Were you trained by other persons who were already performing the kinds of responsibilities that you came to perform?

A. Yes. The manner that the program—I think most everyone that came to the division, in particularly the program specialist was a type of apprenticeship that we [482] would work with people who were already performing those particular duties, and they would obviously give us some basic instructions. They gave us the law and regulations and a number of other items that we would look through. And then we would work directly with those

people reviewing and seeing that the product got reviewed by other people. And eventually we would be given these items to do ourselves. And then they would be screened and reviewed after we had finished to make sure that we had done what we should do and something hadn't been left out. There was a lot of verbal instructions in that situation. And that's basically the way we were trained.

- Q. All right. During the period in which you were trained to perform these responsibilites, were you taught to perform them in the manner you have just described to this court?
  - A. That is the case.
- Q. And I understand that you worked in at least two of the subject matter review sections, if you will, the fungicide-rodenticide section and the herbicide section?
  - A. That's correct.
- Q. And in both you worked—do I understand you to say you worked in both of those sections prior to your being assigned to the ecological investigations branch?
- [483] A. Yes. I worked—my first job on my own, so to speak in the Agency, was to work with the herbicide group. And I worked there something less than a year. Then I was switched over and worked with the fungicide-rodenticide group for somewhat longer prior to being assigned to the ecological investigations branch.
- Q. All right. Did you perform your duties in the manner in which you just described when you were assigned to both of those two subject matter groups?
  - A. That is correct.
- Q. And did other persons assigned to those two subject matter groups and positions similar to yours also perform their duties in that manner?
- A. Yes. Some of those people that actually performed those kinds of duties were the people that helped train me.
- Q. And in the course of your evaluating registration applications in the manner in which you have just de-

scribed, did the patent status of the previously registered chemical make a difference in the manner in which you performed your duties?

A. No, it didn't make any difference. As I think I testified earlier, that at least some of the things that we were told not to become involved with was the patent status of products and what the seller may want to sell them [484] for. I can recall as an example an instance where I saw a five-pound bag of fertilizer with a pesticide in it that they wanted to sell for thirty-five dollars. And I was shocked at that. And the people that I was working with said that it wasn't any of my business.

Q. After you were in the ecological investigations branch did you return to responsibilities for shepherding applications for registration through the Agency?

A. I'm sorry, I missed that question. Would you restate it?

Q. After you were working in the ecological investigations branch did you return to responsibilities for shepherding applications through the Agency?

A. Yes, I did, only not so—so specifically. I became branch chief of the newly formed at that time insecticide and rodenticide branch. So I was the chief. I got involved to some extent, but not to the nitty gritty as I had been in the earlier situation.

Q. And when did you shift to that responsibility from the ecological investigations branch?

A. September of 1971.

Q. Now after you were back in a review branch, were applications for registration handled in the manner that you described when you were describing your performance of your duties during the period 1967 to 1970 or so? [485] A. They were quite similar.

Mr. Heineman. Your Honor, may I object to the question as calling for sheer speculation on the part of this witness. I don't think any foundation has been laid for him—

The COURT. Well, in view of the witness' previous statement concerning the possibility of advising an industrial client, I'm going to overrule the objection. You may answer.

A. Yes. The same review methods were used to have me-too products reviewed as it occurred between '67 and at the time I went to the Ecological Effects Branch, or Investigation Branch. And that was that the program specialist did carry these items to the various reviewers. And they did use their books and the USDA compendium and what have you to generally review the label, review the application without looking at data to make their determination; and on many occasions did personally go to these people and have this done as branch chief, particularly when there seem to be some kind of a problem that did come up.

## [493] By Ms. MULKEY:

Q. Mr. Harrison. I'll show you what has been marked for identification as defendant's exhibit P and I would like in an effort to try to expedite matters to also distribute what's been marked for identification as defendant's exhibits Q, R, S and T at the same time. Mr. Harrison, did you direct that a search be undertaken of Agency files in connection with documentation relating to the Agency's practice regarding me-too registrations in the period prior to the effectiveness of the 1972 amendments to FIFRA?

A. Yes, I did.

Q. Could you describe the nature of the search [494] that you directed be undertaken?

A. Yes. We asked the personnel within the Agency who were here at that time, during that time or may have files that were carried over from that time, to look to see if they could find any documentation that any letters that have been written in regards to patents or use of data or what have you, and in that relationship these particular documents were uncovered, one from Mr.

Alford, the exhibit P, and I believe Q, R, S and T, all were found in Mr. Adamczyk's files. In fact, I think Mr. Alford—Mr. Alford's letter actually was written and then signed by Mr. Alford. So they all showed up in Mr. Adamczyk's files. Mr. Adamczyk is a person that keeps most everything that he writes, and that's why it showed up. I personally do not keep files this long and therefore I didn't have any, if, in fact, I had ever written any such file letters in my tenure in that particular position between '67 and '70.

- Q. Did the search of Agency files extend to individual registration jackets?
- A. No, they did not. That would have been too laborious and time consuming.
- Q. Okay. Now I'd like to direct your attention to what's been marked as defendant's exhibit P.
  - A. Yes.
- Q. And in particular to the last line of the second [495] paragraph: If adequate data is on hand for a formulation further data is not needed.
  - A. Yes.
  - Q. Have you examined this letter?
  - A. Yes, I have.
- Q. And is the statement contained in that sentence consistent with your understanding of the manner in which the Agency conducted evaluations of registrations?
  - A. Yes, it's totally consistent.
- Q. I'd like to direct your attention to defendants' exhibit Q, and in particular to the second sentence of the last paragraph which states: If it is a pesticide that is well known and for which this division has toxicological and efficacy data on hand, such data would not be required to be submitted?
- A. Yes, I see that and it is consistent with the policy which was in existence at that time.
- Q. Are you aware of any special significance that the phrase: "If it is a pesticide that is well known" might

have and in connection with the conduct of registration

applications at that time?

A. Well, obviously if it's a pesticide that we didn't know about, then they would have to submit the data. This is, if it were a new active ingredient this company was going to be submitting.

[496] Q. Did it have any other special significance that you know of?

A. Not that I can think of.

Q. Have you examined the contents of the letter in defendant's exhibit R?

A. Yes, I have.

Q. Do you understand it to be consistent with the practice as you understood it at that time?

A. Yes, I do.

Q. I'd like to turn your attention to the first sentence of that letter: This is in reference to our recent telephone conference regarding compounds whose patents have expired.

A. Yes.

Q. From your experience during this time does anything in that statement have significance with regard to the practice of the Agency regarding consideration of this type of application?

A. No, it's essentially the same.

Q. Turning your attention to defendant's exhibit S and ask you if you have examined that letter.

A. Yes, I have.

Q. And do you understand the contents of that letter to be consistent with the practice as you understood it?

[497] A. That's true.

Q. And to defendant's exhibit T and ask you if you have examined that letter?

A. Yes, I have.

Q. And do you understand it to be consistent with the practice as you have described it?

A. Yes, that's true.

[507] By Ms. MULKEY:

Q. Mr. Harrison, in your opinion does the material relating to toxicity and toxicology of a pesticide contained on a pesticide label, provide the entire scope of general information which an individual might be interested in regarding the toxicity of that chemical if the individual was to be dealing with the chemical?

A. All right, sir. The label basically talks about the acute toxicology of a product and its warnings that relate to that particular item. It does not say anything about the long-term problems that may exist from the use of the product such as whether it may cause cancer or be triogenic or mutagenic or what have you. However, there is a company who now has made application and has requested that we place on their label a statement that this [508] product has shown to cause cancer in animals. And as far as I can recall, sir, that may be the first time that has happened. But generally it does not talk about long-term problems that may or may not occur with that product.

By Ms. MULKEY:

Q. Mr. Harrison, if an individual wished to know the nature of the hazard to fish and wildlife in connection with a pesticide, could he derive that from reading the label?

A. Again, to a certain extent. The label doesn't necessarily tell the applicant what all the problems may be with that product. They will simply say, do not do this or that. Like for instance, do not place this product in water. It doesn't say particularly what all organisms may be affected if you do so. It just simply says don't do that. Because there are problems which really aren't particularly referred to in any extent on the label, so it's simply a direction of how not to use it and so forth.

Q. And with regard to other environmental hazards, does the label describe the nature of the hazards?

A. Generally not. It's just indicating that you shouldn't breathe the product or you shouldn't get it on your skin; or again, with fish and wildlife let's say you shouldn't apply to streams because fish may be killed. But of course there are other things that may be killed, that would occur in a stream too. But it's of a general [509] nature one that the average user, if he follows the directions and the precautions and uses it properly, then there would not be a hazard to the person or the environment involved.

#### CROSS-EXAMINATION

By Mr. HEINEMAN:

Q. Mr. Harrison, in connection with the exhibits DD and EE which you had reference to which were these Aceto registrations on Propachlor—

[510] A. Yes, sir.

Q. [continuing]: —issued on October 4th, 1971, and July 17th, 1972, was Monsanto Company ever advised that those registrations occurred?

A. There was no indication in the record that that happened, as far as I know, unless—let me see—no, I guess there's no record like that, that I can recall in the file. I have no personal knowledge if they were done outside of that.

Q. And at that time there was no provision for any publication of that information, was there?

A. That is correct.

Q. So that as I understand it, Aceto came in and wanted to get a registration on Monsanto's product; they were given that registration and Monsanto Company was never told about it at all?

A. That is correct, as far as I'm able to testify, except as the letter states that was written back when requested by Monsanto to Dr. Early, I believe it was, in 1973, I guess that was the time.

[517] By Mr. HEINEMAN:

Q. With respect to a product upon which Monsanto had been the data submitter on a new chemical—

A. All right.

Q. [continuing]: —prior to this Aceto registration on Propachlor on 1972, was there ever an occasion when a me-too was registered on a Monsanto product?

A. I just don't know.

[551]

Q. It certainly may not. Let me pose this possibility. Let's say that this arbitration thing drags on for five or six years and the me-tooer has been selling since he got the registration. And the arbitration award comes down and it's too much money, he doesn't want to pay it. What does he have to do?

Ms. Mulkey. Objection. Counsel is arguing with the witness.

The Court. On the contrary. He's asking a question. Go ahead.

A. The law as I read it, not being a lawyer, but the law as I read it would indicate that the Agency would then at that time cancel the registration for the me-too product.

By Mr. HEINEMAN:

Q. Or he could just withdraw it, couldn't he?

A. That's another option.

The Court. Supposing he took bankruptcy, what happens?

A. I guess he would be broke, your Honor.

The Court. I know.

A. I suppose that's very possible.

[552] The COURT. Go ahead.

By Mr. HEINEMAN:

Q. So, he can stop selling, he would have to stop selling if you withdrew his registration, right?

A. Legally he would have to stop selling, that's right. Yes, sir.

Q. But he might continue to sell illegally?

A. People do that all the time.

Q. So then let's assume that he obeys the law and he stops. So in the meantime he has been selling Hungarian Glyphosate and making what I'm sure he hopes is a profit on it, and competing with Monsanto and perhaps taking their market away. And then when he finds out the price is too high he quits and he pays nothing. Is that the way the statute works?

A. My reading of the statute would indicate that that is the case.

[560] RAYMOND LANDOLT was called as a witness, and being first duly sworn to tell the truth, the whole truth and nothing but the truth, testified as follows:

[561]

#### DIRECT EXAMINATION

By Mr. McLaughlin:

Q. And you are currently employed in the office of pesticide programs at the Environmental Protection Agency; is that correct?

A. Yes, I am.

Q. And is it correct that you joined the United States Department of Agriculture in 1966?

A. Yes.

Q. And could you trace your Federal service from 1966 to the present time?

A. In March of 1966 I started to work in the Safety Evaluation Staff of the Registration Division of USDA. I was essentially in this position through the period of transition from the USDA to EPA until about 1972, June of 1972 when I was selected from a group of scientists within the organization to do an indepth review on twenty [562] chemicals that were concerned—of concern to the agency.

[564] By Mr. McLaughlin:

Q. Did Dr. Hays ever become deeply involved in the day-to-day activity at USDA?

A. Dr. Hays in his position of wearing two hats, one of division director and the other as branch chief of the Safety Evaluation Division, was a person that took great interest in our activity. Initially we had weekly meetings in the Safety Evaluation Staff to discuss problems. And then inasmuch as the workload was bearing on us, the frequency of these meetings diminished over a period of time.

Q. Did you ever explain to Dr. Hays the way you carried out your activities?

A. No, I did not.

Q. Did Dr. Hays ever give you detailed instructions on how to carry out your activities?

A. No, we did not, neither written nor verbal.

Q. Are you familiar with Mr. Greg Rohwer?

A. Yes. Mr. Rohwer took over as acting director following Dr. Hays.

Q. And did you ever explain to Mr. Rohwer the way you carried out your day-to-day activities?

A. No, I did not.

Q. And did he ever give you detailed instructions on how to carry out your day-to-day activities?

A. No, I saw very little of Mr. Rohwer.

[565] Q. Okay. And are you familiar with Cipriano Cueto, Dr. Cipriano Cueto?

A. Yes, I am. He was the branch chief of the Safety Evaluation Staff.

Q. And again did you ever explain to Dr. Cueto the manner in which you carried out your day-to-day activities?

A. My association with Dr. Cueto was one that would arise when we had problems in our specific sections for which we were doing our reviews.

Q. Okay. Would it be fair to say that you only went to Dr. Cueto when you did have problems?

A. We would seek his advice in requesting data for registration, or in interpreting the data that we had to review.

Q. Okay. You said you were a toxicology labeling data reviewer?

A. Yes.

Q. Could you go into a little bit more detail as to what that job involves?

A. The job involved obtaining an application for registration from one of the registration specialists, and inspecting the label and the contents of the application for completeness before I would start to make my evaluation of the label.

[566] Q. And what was the purpose of your evaluation?

A. The purpose of the evaluation was to determine whether precautionary labeling on the label was adequate for protection of the public; whether the first-aid antidote statement appeared and was adequate; whether the label contained safety claims that may lead to misuse of the product; and where a few use limitations that were pertinent to our evaluation as a safety reviewer.

[569] A. This is a copy of interpretation 18 published March 9th, 1962, in the Federal Register. It is somewhat—the only difference that I recognize in it is in its physical form, in other words, paper rather than in book from that I used.

Q. In other words, you used another printing of interpretation 18 in your day-to-day work; is that correct?

A. Yes, I did.

Q. And this is a version which was published in the Federal Register for public disclosure of interpretation 18?

A. My version?

Q. No, the version which you have?

A. Yes. This appears in all respects like the one that I was using.

Q. Okay. Could you tell me what was interpretation 18?

A. Interpretation 18 is comprised of a number of chemicals that have the most frequent uses that we were concerned with in the registration of pesticides.

Q. And what sort of information did it give?

A. There is—for each one of the chemicals that is listed in here there are break points given for the categories of toxicity that distinguish the different hazards involved from exposure to the pesticide, along with [570] precautionary labeling and first-aid statement.

Q. Okay. You used the term break point. What do you mean by that?

A. That for the particular concentration of the chemical involved is identified with a degree of severity. In other words, the break point, let's say parathion with—formulated as a dust, two percent and below carry the label warning; whereas two percent and above would be labeled with danger, poison, skull and cross bones.

Q. Okay. You mentioned also that you were introduced to another tool in your training called the label file; is that correct?

A. Yes.

Q. Okay. I'd like to show you defendant's Exhibit W. And are you familiar with this exhibit?

A. Exhibit W is copies of my card file that I have accumulated over the years.

Q. Okay. And what sort of information did you—was in this card file?

A. The card file consists of the chemical name of the pesticide identified on each card, along with physical and chemical characteristics of the chemical. There is precautionary labeling, and also identified are the company that has registered the chemical, the concentration of the chemical involved in the formulation, and again the [571] precautionary labeling and the toxicity data that was available on that particular formulation.

Q. Okay. I'd like to direct your attention to page 35 of defendant's Exhibit W. You will note on that page some

material has been blacked out. Could you explain why that material was blacked out?

A. Yes. It was blacked out because I was not certain of the source of the material.

Q. And what do you mean by you were not certain of the source of the material?

A. Oh, I see, okay. It's from a company other than Monsanto.

Q. And how did you select these; how were these cards selected to be included in this exhibit?

A. I went through my card file and pulled out all Monsanto cards.

Q. So, all of the cards in this file were taken from chemicals which had been registered by Monsanto?

A. Yes.

Q. And there is some data on your cards concerning—which could have been submitted by a company other than Monsanto; is that correct?

A. Yes.

Mr. Heineman: Well, your Honor, let me object to that. I think he's speculating. I think he said [572] he couldn't tell for sure who it came from.

The COURT: Well, if he can say it did or didn't he may do so. If he can't say I think he can make a general allegation the part that came from here and part came from there if he knows.

A. If I may, I would turn to page 20. There is a case that I'm really not certain as to which company generated the data. Because there is Lever Brothers at the top and Monsanto at the bottom. And so either one of the companies could have generated it.

By Mr. McLaughlin:

Q. Would it be fair to say that from the face of this card you couldn't tell which data was supplied by which company on that——

A. No, I could not.

Q. [continuing]: —particular registration? Where did you get the information to put on your cards or that is on these cards?

A. Well, I started out with copying the cards of the fellow that was to train me. And then when I had a problem I would go to the other reviewers for information on their card. And knowing full well that I had to operate efficiently at this job I had to accumulate a file that was readily available to me on my desk. The—so the source of information—that source of information was within my group and then as I reviewed each registration that came [573] through that had a bit of data in it I would either make a new card or add that data to the existing card. All of this was to supplement 18, to assist me in my reviews.

The COURT: Let's take ten minutes.

[Whereupon, a ten-minute recess was taken, after which time the following proceedings were had:]

By Mr. McLaughlin:

Q. Mr. Landolt, before the recess we were talking about your training, and you explained the interpretation of 18 and the label file you established. I'd like to ask you a couple of more questions about that period. During your training were you ever instructed—when you were putting together your label file were you ever instructed not to put any data on your label file?

A. No. My data file is my working document to review labels.

Q. And where would you draw the information on that file from?

A. The data that went on my card or label file came from the registration jackets as I would review them, and came from other reviewers, came from the tox file that was available to me, and from the literature.

Q. Okay. And it would then both contain public information and information which was submitted with an application?

A. Yes, it would.

[574] Q. Okay. Were you told at any time there were any restrictions on your consideration of this information in reviewing an application?

A. No, I didn't receive any instruction.

[575] Q. Okay. I'd like to ask you some specific questions about how you performed your review of applications for registration. I believe you testified already that the purpose of your review was to determine the adequacy of the label in presenting the toxicology information which the Agency required to be on the label at the time. Could you tell the Court how you determined the adequacy of the [576] label?

A. Would you like the review process that I went through?

Q. Yes, please.

A. All right. Well, I received the jacket or the registration application, I read the reviewer's comments that had been written prior to my review. I went through the registration application jacket and reviewed the past history of the application. I looked at the confidential formula to see what the inerts and active ingredients consisted of. I read the corresponding letter from the registrant so that I would know what action was being requested. And then my next step would be to draw on the information that I had in interpretation 18, and see if the chemical in question was listed in interpretation 18.

Q. And if it was listed in interpretation 18, then what did you do?

A. If it was listed in interpretation 18 I just compared the percentage break points, the labeling; and if it was satisfactory I would approve it and send it on its way.

Q. Okay. And you would do that for all registrants?

A. For all registrants.

Q. Or all applicants I should have said?

[577] A. Yes.

Q. Okay. If it was not listed in interpretation 18?

- A. Then I would turn to my card file and look up this particular chemical and see just what kind of information I had available to me.
- Q. And what would you do with the information on your card file?
- A. There too I would—it's essentially the same process that I went through with interpretation 18, was to compare the labeling, the percentages of the active ingredients. And also my card file would give me additional information on any other—information on the toxicity of it that I should be aware of.
- Q. And when you used your card file did you consider all information on that card file for all applicants?
- A. I would consider the information pertinent to the registration that I was reviewing.
- Q. And by saying pertinent to the registration you were reviewing, what do you mean by that?
- A. The percentage of active ingredients, and determine whether the precautionary labeling was consistent with what I had on my card file.
- Q. So the curcial factor in whether the information on the card file would be applicable was the identify [578] of the active ingredient; is that correct?
- A. Yes. Each one of my cards was identified with the active ingredient.
- Q. And you were concerned with the active ingredient regardless of the identity of the source of the applicant; is that correct?
- A. That's correct. And also in my reivew I was equally concerned about the inert ingredients, because they too can be toxic.
- Q. And what would you do if you couldn't find any information in your label file regarding that particular active ingredient?
- A. I would see what the other reviewers had in their files and then go to the tox files to see what was in the toxicology or the Safety Evaluation Branch files.

Q. Okay. Going back to the first step, seeing what the other reviewers had in their files, could you go into that in a little more detail?

A. Well, it was a case where we were all sort of communicating with each other as far as exchange of information. And if there was—each one of our files were open for inspection by—well, not inspection but were available to other reviewers, that we had no secrets from each other. Is that what you're referring to?

Q. And if you found information in their card [579] file, what did you do with it then?

A. I would copy it—either copy the card or copy the information. It depended.

Q. And would you then put that information into your card file?

A. Yes, I would.

Q. And if you could not find any information on that particular active ingredient or that particular percentage of the active ingredient in any of the card files of any of the data reviewers, then what would you do?

A. Consult the safety evaluation files. And if nothing was there I would request the data.

Q. What sort of information would you find in the safety evaluation files?

A. The acute studies, acute studies. We had occasionally sub-acutes but by and large there was a limit.

Q. What was the source of this information?

A. This information was gathered on each one of the chemicals that had been submitted by the chemical companies.

Q. Was it primarily public information?

A. No.

Q. It was also information submitted by the company?

A. Yes, it was.

[580] Q. And if you couldn't find any information in that source in the safety evaluation files, then what did you do?

A. I would request the information from the applicant.

- Q. But you would only request the information after you had gone through all those steps; is that correct?
  - A. Yes, I would, that's correct.
- Q. Could you tell the Court how many applications you would process following these steps in one day, a typical day?
- A. Each one of the reviewers varied in their capacity to produce. And the minimum that—expected performance that was considered of each reviewer was twelve a day. I managed to maintain a level of production of about twenty a day. That was not my initial production figure; of course I had to work up to that because it took me a while to develop my capacity to recognize the chemicals and build up my card file where I could be more productive.
- Q. Okay. And during the period from 1966 to 1972 does the procedure you have just described to the Court describe the procedure you followed in your any-to-day review of applications?
  - A. Yes. Yes, that's the procedure we followed.
  - Q. Were there any changes in this period?
- [581] A. Well, in this period we went through the transition of USDA to EPA.
- Q. And upon that transition did you change your procedures for processing applications in any way?
  - A. No, I did not.
- Q. Are you familiar with the compendium of toxicological data which was produced by EPA?
- A. There is a compendium of labeling information and toxicology information.
- Q. Okay. I'd like to show you exhibits—defendant's Exhibit X. Could you identify what Exhibit X is?
- A. Exhibit X is a copy of the looseleaf entries that I prepared for the compendium from my card file.
- Q. Okay. And you compared this compendium—you compared this information; is that correct?
  - A. I prepared it, yes.
  - Q. And for what purpose did you prepare it?

A. This was prepared so that the reviewer could have a ready reference at his desk of all the information on the chemical to assist him in his review of applications for registration. And I drew on all sources that I could to bring forth in one document everything that would assist the reviewer.

Q. And so this document was prepared to assist all of the toxicology reviewers?

[582] A. Yes, it was.

Q. At EPA at that time?

A. Uh-huh.

Q. How did you prepare this document?

A. It came about because of my voluminous card file that I accumulated over the years. I apparently was the prime candidate to do an undertaking like this. And then as I started it I realized that there were certain shortcomings in my own file as far as the current information that would be available in the fungicide and herbicide group, and the disinfectants. And I issued a memo or I made a request of the other reviewers so that I could have the benefit of their information to be incorporated into this compendium.

Q. And did they supply you with information to be incorporated into the compendium?

A. Yes, they did.

Q. And could you tell the Court how the entires for this document, Exhibit X, were selected from the compendium?

A. They are those chemicals that are registered by Monsanto.

[584] Q. Was there my any limitation placed on the sources of your information, toxicology information compiled in this compendium?

A. No limitations.

Q. And you drew it from all sources?

A. From all sources available to me to the point of citing PR notices for reference to the reviewer, references

to information that is available in the literature, any and everything, even citing interpretation 18 so that the reviewer would know that this particular chemical does appear in interpretation 18.

Q. And in addition to public literature, would information which was obtained from registrant's files be in this document?

A, I'm sorry?

Q. In addition to the information which had appeared in the public literature, would information which had been obtained from a registrant's files, but had not appeared in the public literature, also be part of this document?

A. Yes, it is.

[586]

#### CROSS-EXAMINATION

By Mr. HEINEMAN:

Q. Mr. Landolt, as I see Exhibit No.—or defendant's Exhibit X here, that appears to be summaries of data, is it not? It's not raw data submitted by the applicant, is it?

A. Inasmuch as defining the quality of the data, no, it doesn't give that kind of information.

Q. Well, for example the toxicological study that is submitted in support of a registration, those studies can take up to fifty-three months to do. Now surely they don't submit in support of a registration something that's like that, do they, half a page long?

A. No.

Q. So what you've done is you've looked at somebody's data and then you've written down a summary that contains label cautions and then acute toxicity information?

A. That's correct.

[590] Q. All right. Now do you know the difference between a commodity and a proprietary chemical?

A. Prior to coming into this courtroom this afternoon I have never heard of those two terms referred to [591] in regard to pesticides.

[593] Q. In connection with your Exhibit W you've got these places you referred to where certain data was blacked out and you didn't know where you got it from. Is that the reason it was blacked out, you couldn't tell for sure whether it was Monsanto's or somebody else's?

A. No, that was Lever Brothers and Monsanto. That was the card that had Lever Brothers and Monsanto on it.

Q. Right. Did you know that Lever Brothers was a customer of Monsanto's for chlorinated triazines?

A. No, I did not.

Q. Do you know whether or not Lever Brothers had Monsanto's permission to obtain a label for a chlorinated triazine?

A. No, I did not.

Q. Do you know whether or not the chlorinated triazines were used as herbicides?

A. No, I can say I really don't recall what uses the triazines had.

[594] Q. Let me direct your attention particularly to page 26 of Exhibit W. Do you know where you got that information?

A. From the Chemical and Engineering News, November 29th, 1971.

Q. Was that chemical listed there ever registered with the EPA?

A. I have no idea.

Q. Let me direct your attention to page 28, and what we have there is apparently a sodium salt of 2-mercaptobenzothiazole; is that correct?

A. Apparently, yes.

Q. Is that a pesticide?

A. I suspect it's a fungicide.

Q. Do you know if Monsanto Company ever used it or

registered it as a pesticide?

A. No, I do not. However, I do see from Monsanto's technical bulletin there is a citing of data and some comments on it in the middle of that page.

Q. Right. You got that from a technical bulletin?

A. That's my source.

Q. What is a technical bulletin?

A. Oh, a piece of literature generated by the company for distribution to their clients.

[595] Q. It's a way by which they tell their customers some information about their products?

A. Uh-huh.

Q. Let me direct your attention to page 56. What is represented on that page?

A. Well, we have rodenticide by the common name of Warfarin and registration number by Monsanto of 52469.

#### By Mr. HEINEMAN:

Q. What is that?

A. Anticoagulant.

Q. Is it a mouse killer?

A. I have it identified on the page as a rodenticide.

Q. Do you know where Warfarin came from?

[596] A. I suspect—I think it was a product produced by WARF Institute

Q. Which is the University of Wisconsin Alumni Research Foundation?

A. Thank you. Yes, sir.

[601] JAMES CODY NELSON [602] was called as a witness, and being first duly sworn to tell the truth, the whole truth and nothing but the truth, testified as follows:

#### DIRECT EXAMINATION

By Ms. MAYER:

[603] Q. Okay. Could you briefly describe your duties as an attorney with the Grants, Contracts and Administration division at EPA's Office of General Counsel?

A. Yes. My primary responsibility was to work with the Freedom of Information Act, the Privacy Act, and issues related to the confidentiality of business information. We also had other duties that related to Grants and Contracts, other general personnel matters. The Division was sort of a general practice office of the Agency. My primary work, though, was with the Freedom of Information Act, confidentiality of business information. It included giving advice to the various offices in the Agency on those matters, as well as the formal duty of drafting the legal opinions on appeals of Freedom of Information Act requests that were made in the [604] Agency.

[612] A. \* \* \* If the request were for data that had been submitted by an applicant or a registrant under FIFRA, there is a provision of the statute, section 10(g), which provides that the requester must submit an affirmation which, in essence, states that the person making the request is not a foreign or multi-national pesticide producer, and that the person is not an agent for such a producer, and that the person will not negligently or willfully make the information available to such a person. I think we can read that specific language later, if you would like. The affirmation requirement applies to any requester requesting data submitted by an applicant or registrant. If there is an affirmation included within the original request letter, then the office would proceed to the next step, processing the request. If there is no affirmation, they would write back to the requester, saying we cannot further process your request until you submit such an affirmation. And they would send a copy of the form affirmation that we use back to requester, assuming that the requester has signed and submitted an affirmation either with [613] the original request or in response to our communication. The people in that branch would evaluate the affirmation of the requester to ascertain whether the person, in spite of having signed the affirmation, might be a multi-national or foreign producer, or an agent for such a person. If they were to determine that the person did not qualify under Section 10(g), they would write back to the requester denying the request on the basis that we are not allowed to disclose the information under Section 10(g).

The Court: Excuse me. Have you ever had any litigation as a result of refusal?

A. We have not, your Honor. We have denied a number of requests on the basis that the requester was not qualified under 10(g) to receive the information. And none of them have ever filed suit against us.

[638] Q. From your experience, could you describe the types of persons who have requested information through the Freedom of Information Act, for data submitted under FIFRA?

A. We have received requests from an infinite variety of people. We have received some requests from companies either in the pesticide business or some other business. We receive many requests from law firms, many of them representing companies in the pesticide business. We receive requests from a very interesting firm that has an office in Rockville, Maryland called FOI Services. And their entire business is making FOI requests on behalf of anonymous parties who don't want the Agency to know who's making the request.

The Court. Can you put them in jail for perjury for signing—

A. Well, that's the thing. What we found when [639] we asked FOI Services to sign the affirmation, they typically withdraw their request because the whole reason the client goes to them is to maintain their anonymity. And the affirmation from itself requests the identity of the client. And since the client doesn't want to be known, our experience has been that very few of the requests that

come from FOI Services ever get beyond that stage. Many of the requests have come in from legal representatives or offices of the unions representing either farm workers or chemical workers. We have received some requests from individual citizens. We have received requests from environmental and conservation groups such as the National Audubon Society.

By Ms. MAYER:

Q. Could you continue your answer? Were there any other groups that you were—

A. We received an occasional one. We had some requests from companies who were involved. You heard testimony yesterday on the whole thing of data compensation. We [640] occasionally get requests from companies that's being asked to pay compensation to get a look at the data that they're being asked to pay compensation on. That's one particular example. I have also had an occasion that I have worked on where some local pesticide distributors were trying to pursue an anti-trust action against the pesticide company because they cut off his supply, or something. And they told him the reason was because of something EPA had done in regulating pesticides. So he had written in and asked for the data so he could understand.

The COURT: As I understand it, you're not going to concern yourself with patent, anti-trust or anything of that nature; is that a fair statement?

A. Yes. We do not look into the purpose of the request except to the extent that 10(g) is relevant, of course.

By Ms. MAYER:

Q. Okay. Mr. Nelson, you have stated that you sometimes get requests from pesticide companies or law firms representing pesticide companies. What type of information do they generally request?

A. Well, in the past, certainly before the 1978 amendments of FIFRA, we got a lot of requests from companies basically interested in looking at another company's data.

And by data there, I mean the health and safety data we were referring to. Almost all of them knew along the way that they were not going to get product formulas and things like [641] that. We got many requests for the data, animal studies, residue studies, and so on. After the '78 amendments, once we started sending out letters telling people they had to submit the 10(g) affirmation, what we have seen happen is that the number of requests from companies after-asking for the actual data has dropped considerably. Most of the requests we're now receiving from the companies are for fairly routine items, such as copies of labels that the agency has approved, copies of documents that are used in the RPAR process, and so on. And apparently the companies have all recognized that almost none of them can qualify any more under 10(g), because almost all of them have some foreign business connection and, thus, are not eligible under 10(g). And they have stopped making any requests for the health and safety data because they know they couldn't get it. And instead they're requesting things that are basically public, like the labels.

Q. Eliminating these routine requests for labels, how many of the requests that you get for actual data come from companies in business or law firms representing those companies and, on the one hand, versus groups like union groups or citizens groups, on the other hand?

A. I would say that no more twenty percent of the requests for the health and safety data itself now comes from companies or their representatives.

[642] Q. Do you get requests from scientists and doctors?

A. Yes. We have had requests from scientists. I'm trying to—I can't remember the name, it's a big research institute in New York. I forget the name of it right now. But some people from there requested some data. We have received a few requests from physicians who were concerned about patients who may have been exposed to pesticides, and they wanted to look at the data to see what the effects might be and whether the things their

patients were experiencing were the result of pesticide exposure.

[648]

#### CROSS-EXAMINATION

By Mr. DYER:

- [651] Q. I see. All right. While I'm on this point, and we'll get to it in a bit more detail later. You also have testified to some length about the so-called 10(g) affirmation which was marked as an exhibit here in the proceedings this morning. Is that a regulation?
  - A. The 10(g) affirmation?
  - Q. Yes.
  - A. No, the affirmation is not a regulation.
- Q. I see. Are there specific regulations that have been promulgated pursuant to 10(g)?
- A. There are no regulations since the amendment of our FOI regulations in, I believe, September of '78.
  - Q. Well--
- A. That's prior to the FIFRA amendments. So there have been no FOI regulations specifically to the '78 amendments to FIFRA.
- Q. Mr. Nelson, my question though is have there been regulations promulgated pursuant to section 10(g) of FIFRA of 1978?
- A. There have not been regulations promulgated about section 10(g). I don't know that regulations have been promulgated pursuant to section 10, but there are no regulations about 10(g).
- [652] Q. Now, we're all aware that the subject of section 10(g) deals with foreign or multi-national pesticide producers?
  - A. Right.
- A. Has the Agency promulgated a written definition of what that term is?

- A. There is no definition other than what appears in the interim procedures which is the statutory language.
- [653] Q. Are you familiar with a company that's located in Kansas City, Kansas called Thompson Hayward Chemical Company?

A. Yes, I have some—I mean I know who they are. I know they're in the pesticide business.

Q. Would they, under your interpretation of foreign or multi-national, be a foreign or multi-national pesticide producer?

A. I don't recall whether we have ever had to rule on that. I would have to know more facts about them, where their business is, what they do, and so on. The fact that they're in the U.S. alone doesn't mean they're not; but I would have to know what foreign business they have.

Q. All right. Then since you don't know about Thompson Hayward specifically, let's take it from the other side. You say it's apparent what a foreign or multi-national pesticide producer is; what is a non-foreign or multi-national pesticide producer in the EPA's interpretation? Can you tell [654] me that?

A. Well, firstly, every company that has nothing to do with pesticides, anyone who's not—

Q. Let's limit it to pesticide companies.

A. Okay. The company whose business is solely in the U.S., does no exporting would not be.

Q. Any others, any other requirements?

A. Not that I can think of.

Q. Let's assume that one of those companies that fits your interpretation at some point in time makes a request for data, and because they are not a foreign or multi-national pesticide producer, they quite properly sign the affirmation. And data is then—ultimately, after your procedures have all been followed correctly and exhausted, pesticide data is disclosed to them by the Environmental Protection Agency. Now let's further assume that at some point in time, maybe years down the road or

maybe not so long, that company is acquired by another company that is in fact a foreign or multi-national pesticide producer. What happens in that situation?

A. EPA's action is complete so nothing would happen from our point of view.

[658] By Mr. DYER:

Q. I want to draw your attention to the language in 10(G) which I believe is in fact that last sentence. And it says in part, notwithstanding any other provision of this subsection, the Administrator may disclose information to any person in connection with a public proceeding under law or regulation, and so on?

A. Uh-huh.

[659] Q. Now what's a public proceeding?

A. Well, I'll have to refer you to our interim policy where we talk about how we will implement that.

Q. Well, let me ask you this. I'm sure you're familiar with a procedure that EPA has developed over the years called rebuttable presumption against registration, and goes by the term RPAR?

A. Uh-huh.

[659] Q. Is that a public proceeding?

A. I do not specifically work on the RPAR proceedings so I don't know if that would be characterized as one under this.

Q. Well, all right. There are provisions in other sections of the statute dealing with procedures by which the registration of a pesticide may be cancelled. And they have come to be known as cancellation proceedings, and they are in fact administrative proceedings which have been held. And I think in fact one is going on now, at least one where hearings are held, and so forth. Now, are those cancellation proceeding public proceedings?

A. Again, I don't have special expertise in those proceedings. There are aspects of them that are public, but I'm aware of a particular proceeding involving Dow Chemical and 2, 4, 5-T where in fact some of the matters in it have been sealed or held in confidential sections.

Q. But isn't it true, Mr. Nelson, that the reason that those documents in the *Dow* case were presented—were disclosed by Dow under a protective order was because at the time, the Dow Chemical Company had an injunction in the Eastern District Court in Michigan which enjoined the EPA from disclosing their data, and wasn't that the purpose of the protective order in that case?

A. That is my understanding.

[661]

- Q. All right. Now, I may be confused and I want both myself and the record to be clear. You were talking about the types of requests that you got from pesticide companies. And I believe you said that prior to the '78 amendments you got a large volume of requests for data from pesticide companies. Well, Mr. Nelson, under the 1972 amendments to FIFRA and also the 1975 amendments, didn't section 10 at that time protect trade secret data?
- A. Well, that would call for a judgment on—certainly data was always protected under section 10(b), some data. Now what data that was in fact, the agency has extensive [662] litigation with companies over whether or not health and safety fit within that.
- Q. And didn't that litigation ultimately result in the conclusion by at least three or four courts that what you characterize as health and safety data was in fact trade secret within the definition of the restatement of torts, and was in fact protected; and further, wasn't the Agency enjoined from disclosing data of at least two or three of those chemical companies?
- A. There were decisions to that effect, but that doesn't prevent people from making requests.
- Q. Well, if there were these large volumes of requests made prior to '78, were you disclosing this trade secret data prior to 1978?
  - A. Very little, if any, data was being disclosed.

Q. Now, I want to ask you again as briefly as I can about one other area. You have been here in the court-room for the last two or three days, and no doubt have heard reference made to, and certainly have seen sitting over there on that cart, a rather large volume of pesticide data which has been described as the data submitted by Monsanto Company in support of registration on its product called Roundup. In connection with that I want to hand you a copy of what was previously marked Plaintiff's Exhibit 39, and I'd ask you to take a look at that.

Q. Now, in reviewing Exhibit 39, would it be your opinion that the information contained therein would not be disclosable under the 1978 amendments to FIFRA under section 10 or 3?

A. Let me say two things about it. There are some things on it that clearly are not confidential, like the identity of the pesticide-the chemical identity of the active ingredient. I don't think anyone is alleging those are confidential. The chemical properties of the active ingredient resumably are not confidential also. There is the composition of the formulated product, and that is one of the things that can be confidential under the '78 amendments. It's not automatically confidential but assuming the company can show that [664] it is, it can be treated as confidential under the statute, and is not required to be disclosed. Same thing with respect to manufacturing process which appears on the second page. And I'm not exactly sure what the rest of the document is about. At the bottom of that page, it's talking about some kind of test and I'm not sure what it's testing, because I'm not a chemist. It says determination of N-phospho. blah, blah, blah, blah, and I'm not sure if this is some physical chemical property test or whether this is a health and safety test, so I couldn't tell you what the status of that last part would be. But it does describe some method for testing something. It might be a method for identifying an inert, in which case it would be eligible

for confidential treatment. And it might be a thing that is merely telling you something about the properties of the pesticide vis-a-vis mammals or fish or something, in which case it wouldn't be. But I couldn't tell you without knowing more about it. Again, it's a case where you would have to tell me as the company if it's confidential and why; and then I would have to evaluate that.

Q. That was going to be my next question. If you were still employed in your job that you had prior to December, 1979 where you were dealing with these matters, would you be [665] called upon—and assuming that it were requested and Monsanto asserted confidential treatment, would you be called upon to make a determination as to whether that document was in fact protected?

A. Certainly.

Q. All right. Now, I want to direct your attention over there to all those other documents. And I realize at the outset that you—at least I presume that you have never had an opportunity nor a desire nor a reason to review all those documents?

A. No, I haven't.

Q. And I'm certainly not going to ask you to do that at this time. But I want to represent to you that there has been testimony that the information contained in those documents is in fact the information, research and test data which the Monsanto Company has submitted to the Environmental Protection Agency in support of its registration on the pesticide Roundup. And I also want to represent to you that several categories of information, research and test data are contained in those documents. And I want to go through those categories of documents, and I want you to assume that that particular type of information is in fact represented there. And I want to then ask you whether, assuming requests were made and your procedures were followed, whether that particular type of information would be disclosable under section 3 or 10 of the 1978 amendments to FIFRA?

A. Let me just, as a preliminary question, again [666] just to set the stage, this is a registered or previously registered pesticide?

Q. Roundup? It is a registered pesticide.

A. So 10 would apply?

Q. It would. We will further assume that. That is a fact. What about the category of information, research and test data characterized as efficacy studies; would those be disclosable under section 10?

A. With the caveat that material described in 10(d)(1) (A), (B), (C) is not required to be disclosed, my understanding of what you're referring to as efficacy data would fall within the description of 10(d)(1).

Q. What about the category known as phytotoxicity data?

A. I heard that term yesterday and I'm not sure what it means. If you wouldn't mind explaining the term to me?

Q. Well, I wouldn't do that. If you don't know then you can't at this time make that determination. What about metabolism and residue studies?

A. My understanding is that metabolism and residue studies again would fall within 10(d)(1).

Q. What about environmental chemistry data?

A. My understanding is that has to do with fate and the environment, and that would fall within 10(d)(1).

[667] Q. What about toxicology studies?

A. That would fall within 10(d)(1).

Q. What about fish and wildlife studies?

A. That would fall within 10(d)(1).

Q. And so then is it fair to say, Mr. Nelson, if you will assume that the categories I have just described are what is comprised in that mass of information, research and test data except that which is set out in Exhibit 39, then is it not a fact that under section 10 of the 1978 amendments to FIFRA, all of that data would be disclosable?

A. To people who qualify under 10(g).

Mr. Dyer. Right. That's all the questions I have.

#### Plaintiff's Exhibit 6

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# Supreme Court of the United States No. 83-196

WILLIAM D. RUCKELSHAUS, ADMINISTRATOR, UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, APPELLANT

v.

#### MONSANTO COMPANY

Appeal from the United States District Court for the Eastern District of Missouri.

The statement of jurisdiction in this case having been submitted and considered by the Court, in this case probable jurisdiction is noted.

**ОСТОВЕК** 11, 1983.

Justice White took no part in the consideration or decision of this case.

IN THE

# Supreme Court of the United States

OCTOBER TERM, 1983

WILLIAM D. RUCKELSHAUS, ADMINISTRATOR, UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, Appellant,

V

Monsanto Company

On Appeal From The United States District Court For The Eastern District Of Missouri

#### MOTION TO AFFIRM

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#### THE QUESTION PRESENTED

Whether the disclosure and private use provisions of the 1978 amendments to the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C §§ 136a(c)(1)(D), the last sentence of 136a(c)(2)(A), 136h(b), and 136h(d) (1982)) violate the Fifth Amendment to the Constitution by taking private intellectual property in the form of trade secrets for private use, without just compensation, and without due process of law.

#### THE PARTIES

Monsanto Company's non-wholly owned subsidiaries and affiliates, pursuant to Supreme Court Rule 28.1, are:

ACM Services, Inc.
Collagen Corporation
Soperton Gum Market, Inc.
Advent Eurofund Limited (UK)
Australian Fluorine Chemicals Pty. Limited
Biogen N.V. (Netherlands Antilles)
Companhia Brasileira de Estireno (Brazil)
Companhia Brasileira de Plasticos Monsanto (Brazil)
Daishin Kogyo K.K. (Japan)

Goyana, S.A. Industrias Brasileiras de Materias Plasticas (Brazil)

Hydrocarbon Products Pty. Ltd. (Australia)
Industrias Resistol, S.A. (Mexico)
Korag Company Limited (Republic of Korea)
Korsil Company, Ltd. (Republic of Korea)
Mitsubishi Monsanto Chemical Company (Japan)
Monsanto Chemicals of India Limited
Monsanto (Malaysia) Sendirian Berhad
102957 Canada Limited
Revertex Industries (N.Z.) Ltd.

## TABLE OF CONTENTS

		Page
STA	TEMENT OF THE CASE	1
	FIFRA's Historic Protection of Trade Secrets	2
	The 1978 FIFRA Amendments	
	Litigation Arising from EPA's Implementation of the 1978 Amendments	6
	The Proceedings Below	7
ТнЕ	QUESTION PRESENTED WAS CORRECTLY RESOLVED BY THE DISTRICT COURT	9
I.	Monsanto's Trade Secrets Are Constitutionally Protected Property	10
II.	THE 1978 AMENDMENTS TO FIFRA TAKE MONSAN- TO'S TRADE SECRET PROPERTY	15
III.	FIFRA'S TAKING OF MONSANTO'S TRADE SECRET PROPERTY VIOLATES THE FIFTH AMENDMENT'S "PRIVATE USE" LIMITATION	20
IV.	"JUST COMPENSATION" IS NOT PROVIDED FOR THE TAKING OF MONSANTO'S TRADE SECRET PROPERTY	23
Con	CLUSION	28
APP	ENDIX A	1a

# TABLE OF AUTHORITIES

Cases	Page
Andrus v. Allard, 444 U.S. 51 (1979)	19
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### **Table of Authorities-Continued**

	Page
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1983)	24
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(1945)	24
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7 U.S.C. § 136h(d)(1) (1982)	4
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### **Table of Authorities-Continued**

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### IN THE

## Supreme Court of the United States

OCTOBER TERM, 1983

No. 83-196

WILLIAM D. RUCKELSHAUS, ADMINISTRATOR, UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, Appellant,

v.

MONSANTO COMPANY

On Appeal From The United States District Court For The Eastern District Of Missouri

### MOTION TO AFFIRM

Pursuant to Supreme Court Rule 16, Monsanto Company moves that the judgment of the district court be affirmed.

#### STATEMENT OF THE CASE

This case involves the unconsented disclosure and private use of pesticide trade secrets. Monsanto Company owns trade secrets consisting of information, research and test data regarding the chemistry, metabolism, degradation, toxicology, and residues of Monsanto's commercially valuable pesticides. In view of the fact that pesticides account for more than 90 percent of Monsanto's operating income, protection of these trade secrets is vitally important to Monsanto's commercial success. As a result of drastic revisions in 1978 to the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), 7

U.S.C. §§ 136 et seq., under which Monsanto's pesticides are approved and registered with the federal government, Monsanto faced the imminent loss of this trade secret property.

Monsanto filed suit challenging the constitutionality of these 1978 FIFRA amendments which required, for the first time in the history of this statute, the disclosure and use of Monsanto's trade secret information, research and test data for the benefit of the company's competitors. See 7 U.S.C. §§ 136a(c)(1)(D), 136a(c)(2)(A), 136h(b), and 136h(d) (1982). After a full trial on the merits, the district court entered a judgment finding that these provisions violate the Fifth Amendment and the Taking Clause and enjoining their implementation. J.S. App. 28a-37a. This is a direct appeal from that judgment.

FIFRA's Historic Protection of Trade Secrets. For nearly thirty years before the 1978 amendments, trade secret research submitted under FIFRA was fully protected from unconsented disclosure or use. Under the original FIFRA enacted in 1947, the U.S. Department of Agriculture ("USDA") carefully preserved the confidentiality of trade secrets while evaluating and registering thousands of pesticides. Contrary to EPA's assertion (J.S. at 4 & n.3), expert testimony at trial showed that USDA consistently kept trade secrets confidential and refused to use one company's trade secrets for the benefit of its competitors. J.S. App. 26a-28a. All pesticide producers were required to submit their own research and test data or data from the public literature in order to obtain registrations.

<sup>&</sup>lt;sup>1</sup> References to the district court's findings of fact and decision are cited as "J.S. App. 1a-37a." Emphasis is added unless otherwise noted.

Congress reaffirmed FIFRA's historic protection of trade secrets in 1972, two years after the Environmental Protection Agency assumed responsibility for pesticide regulation. See Federal Environmental Pesticide Control Act of 1972, Pub. L. No. 92-516, 86 Stat. 973 (1972), These 1972 FIFRA amendments expressly prohibited EPA from disclosing trade secret research and data, and prohibited competing producers from obtaining pesticide registrations on the basis of their competitors' trade secrets without the owners' consent. In reaffirming this protection of trade secrets from unconsented disclosure and private use, Congress adopted "the definition of 'trade secret' as incorporated in the RESTATEMENT OF TORTS [§ 757]." S. Rep. No. 92-838 (Part II), 92d Cong., 2d Sess., at 72 (1972). See, e.g., Chevron Chemical Co. v. Costle, 443 F. Supp. 1024 (N.D. Cal. 1978).

Despite these 1972 amendments, EPA subsequently rejected following the Restatement definition of trade secrets. Trial Exh. 29 (Mem. of Robert V. Zener, EPA General Counsel). During oversight hearings, EPA was severely chastised by Congress for being "bitterly opposed" to the statutory prohibitions regarding the disclosure and use of trade secrets. Hearings Before the House Committee on Agriculture on FEPCA Implementation, 93d Cong., 1st Sess. 11-12 (1973) (Rep. Poage, Chmn., House Agriculture Comm.) ("Hearings"). EPA nevertheless began automatically rejecting all claims of trade secret protection for private information, research and test data, prompting judicial decisions that compelled EPA to halt this practice and accept Congress' 1972 adoption of the Restatement's definition of trade secrets. Mobay Chemical Co. v. Costle, 447 F. Supp. 811 (W.D. Mo. 1978). See also Dow Chemical Co. v. Costle, No.

76-10087 (E.D. Mich. Nov. 16, 1977); Chevron Chemical Co. v. Costle, 443 F. Supp. 1024 (N.D. Cal. 1978).<sup>2</sup>

The 1978 FIFRA Amendments. Congress again amended FIFRA in 1978, enacting the trade secret disclosure and use provisions found unconstitutional in this case. Federal Pesticide Act of 1978, Pub. L. No. 95-396. §§ 2 and 15, 92 Stat. 819 (1978). Amended sections 10(b) and (d) drastically altered FIFRA by removing the former restraints on EPA's disclosure of trade secret information, research and test data required from pesticide companies, and directing that all such data "be available for disclosure to the public." 7 U.S.C. § 136h(d)(1) (1982). The last sentence of amended section 3(c)(2)(A) also requires EPA to "make available to the public" all of a manufacturer's submitted research and test data within 30 days after a pesticide is registered. 7 U.S.C. § 136a(c)(2)(A)(1982). While EPA describes the potential beneficiaries of disclosure as "qualifying members of the public" (J.S. at 2), the record developed in this case demonstrates that Monsanto's business competitors can and would receive Monsanto's trade secrets through these provisions. Trial Exh. 14, 47-51; Tr. 218, 250-51. See also Original Deposition of Clausen Ely, Jr.

<sup>&</sup>lt;sup>2</sup> Congress also amended FIFRA in 1975. Act of Nov. 28, 1975, Pub. L. No. 94-140, 89 Stat. 751 (1975). These amendments resolved against EPA a similar controversy over EPA's announced view that the 1972 FIFRA trade secret use restrictions applied only to data submitted to EPA after 1972. See 38 Fed. Reg. 31862, 31863 (1973).

<sup>&</sup>lt;sup>3</sup> At the same time, Congress enacted a number of additional provisions, not at issue here, designed to expedite EPA's registration functions in light of EPA's failure to implement various 1972 amendments, as well as provisions permitting "conditional registration" of pesticides and transferring primary enforcement responsibility to the states. Pub. L. No. 95-396, §§ 6 and 26, 92 Stat. 819 (1978).

The 1978 amendments similarly abandoned the 30-year-old requirement that a pesticide manufacturer submit its own research and test information or data from the public literature. Instead, section 3(c)(1)(D) now awards private pesticide firms a nonconsensual "piggyback" or "free ride" on trade secret research generated and previously submitted to EPA by their competitors: new or corroborating test data is no longer required for EPA approval of pesticide applications. 7 U.S.C. § 136a(c)(1)(D) (1982).

As part of these new provisions, the 1978 FIFRA amendments created a limited private compensation/ arbitration scheme for trade secrets submitted under FIFRA after 1969. 7 U.S.C. § 136a(c)(1)(D)(ii) (1982). Those competitors who use another's trade secret property for obtaining their own domestic pesticide registrations must in certain instances offer compensation to the owner of the trade secrets. Id.; 7 U.S.C. § 136h(d) (1982). If the offer is unacceptable, the owner can be compelled to submit to binding arbitration without judicial review. The owner forfeits any compensation by refusing to do so. 7 U.S.C. § 136a(c)(1)(D)(ii) (1982), and competitors who use disclosed trade secrets outside the registration process need not even offer compensation. Frequently, the trade secret owner would receive no compensation whatsoever for its property. J.S. App. 36a.4

<sup>&</sup>lt;sup>4</sup> Among other limitations on this private compensation scheme, when arbitration is required FIFRA does not specify any "formula or other guidance on the valuation of data for compensation purposes." 45 Fed. Reg. 55394 (1980); J.S. App. 21a, 34a. In addition, no compensation is required for use of data submitted before 1970, for any data fifteen years after submission, or for competitors' private use of the data for purposes other than domestic "free ride" pesticide registrations. 7 U.S.C. § 136a(c)(1)(D)(iii) (1982).

Litigation Arising from EPA's Implementation of the 1978 Amendments. After enactment of these disclosure and use amendments, EPA promulgated regulations compelling all companies seeking registration to cite or refer to their competitors' trade secret information, research and test data. 40 C.F.R. § 162.94, 5 (1979). In effect, these mandatory "cite-all" regulations sharply magnified the frequency with which the amended FIFRA provisions would require the private use and disclosure of trade secrets.

The legal challenges prompted by EPA's mandatory "cite-all" approach first invalidated EPA's regulations for failure to comply with the Administrative Procedure Act, without reaching their substantive validity. Mobay Chemical Co. v. Gorsuch, 682 F.2d 419 (3d Cir.), cert. denied, 103 S. Ct. 343 (1982). EPA then re-proposed identical regulations, 47 Fed. Reg. 57635 (1982), but in the meantime the original regulations were invalidated for substantive inconsistency with FIFRA. National Agricultural Chemicals Association v. EPA, 554 F. Supp. 1209 (D.D.C. 1983). The NACA court held that the 1978 amendments permitted, but did not compel applicants to use their rivals' data. Companies so choosing could still seek registration based solely on their own data or data in the public domain. Id.

EPA did not appeal the NACA decision, and the judgment in that case relieved much of the pressure EPA itself had created to disclose and use competitors' trade secret property. In addition to the controversy over EPA's mandatory "cite-all" regulations, courts were considering a number of constitutional challenges regarding

the 1978 trade secret amendments to FIFRA. Meanwhile, this case was proceeding to judgment.

The Proceedings Below. Monsanto filed this suit shortly after enactment of the 1978 amendments, upon discovering that its trade secrets were about to be used to register a competitor's pesticide. In the first decision to consider fully all the issues and following four years of litigation, the district court entered a limited injunction with respect to FIFRA's disclosure and private use amendments, 7 U.S.C. §§ 136a(c)(1)(D), 136h(b) and (d), and the last sentence of 136a(c)(2)(A) (1982). Based on detailed testimony at trial, numerous depositions, ex-

<sup>&</sup>lt;sup>5</sup> One district court held aspects of FIFRA's compensation/arbitration mechanism unconstitutional; other courts have decided various challenges without reaching both the "taking" and "just compensation" questions decided in this case. Compare Union Carbide Agricultural Products Co. v. Ruckelshaus, No. 76 Civ. 2913 (RO) (S.D.N.Y. July 28, 1983) with Chevron Chemical Co. v. Costle, 641 F.2d 104 (3d Cir.), cert. denied, 452 U.S. 961 (1981); Mobay Chemical Corp. v. Costle, 682 F.2d 419 (3d Cir.), cert. denied, 103 S. Ct. 343 (1982); Petrolite Corp. v. EPA, 519 F. Supp. 966 (D.D.C. 1981).

<sup>&</sup>lt;sup>6</sup> See Trial Exh. 47 and 50. Throughout this litigation, Monsanto has continued to be threatened with the disclosure and use of its trade secrets. Although EPA has been prohibited from disclosing and conferring Monsanto's trade secret data on competitors during this litigation, see Justice Blackmun's opinion denying EPA's stay application, App. A infra, EPA's lapses still have resulted in several disclosures under the 1978 amendments. Among those, EPA disclosed certain Monsanto test data in response to a request from a private attorney on May 7, 1982 and to Pesticide and Toxic Chemical News for a story appearing June 15, 1983. After the first incident, the district court ordered EPA to show cause why its Administrator should not be held in contempt, and on August 31, 1982, EPA consented to an order further restricting EPA's treatment of Monsanto's trade secret data.

hibits and other evidence, the district court held that these FIFRA trade secret provisions resulted in an unconstitutional taking of Monsanto's property for a private use and without just compensation, thus violating the Fifth Amendment.

At the outset, the court found that Monsanto possesses constitutionally protected trade secret property rights in its valuable information, research and test data. J.S. App. 30a-31a. Not only does the property constitute trade secrets under the definition set forth in the Restatement of Torts § 757 and Missouri law, but EPA itself did "not controvert the fact Monsanto enjoys certain property rights in its information, research and test data." Id. The court then ruled that the 1978 FIFRA amendments resulted in a "taking" of that property because they "effectively destroyed" Monsanto's trade secret rights, and gave "Monsanto's competitors a free ride at Monsanto's expense." J.S. App. 31a-33a. Finally, the court held that this taking violated the Taking and Due Process Clauses, on the alternative grounds that the 1978 amendments transfer Monsanto's property for the impermissible "private use" of business competitors, and that neither FIF-RA's compensation/arbitration scheme nor any other source would provide "just compensation" for the taking of Monsanto's property. J.S. App. 31a-32a, 34a-36a.

The district court's amended judgment operates only to protect trade secret property and in no way affects EPA's ability to make safety determinations. Throughout this litigation, Monsanto has never challenged EPA's requirements under FIFRA for an applicant to submit adequate information to justify registration, nor has Monsanto challenged EPA's use of trade secret research to disapprove unsafe or ineffective pesticides. Moreover, recent EPA guidelines, issued in response to the NACA decision

and the district court's judgment, see page 6 supra, confirm that notwithstanding the protection of trade secrets, pesticides can still be registered with the producer's own data, public data, or with consensual use of another's data. 48 Fed. Reg. 32012 (1983) (announcing Pest. Reg. Notice 83-4). In EPA's own words, "the[se] procedures make it possible for an applicant to satisfy [FIFRA's] registration data requirements . . . [while] the Agency will remain free to evaluate all relevant data in its files." Pest. Reg. Notice 83-4 at 1. Thus, EPA's implication that the transfer and destruction of trade secret property is essential to administering a pesticide registration program is contradicted by both EPA's own recent guidelines and the history of FIFRA.

Despite the fact that EPA is continuing to register, deny, cancel, and suspend various pesticides, EPA applied to this Court for a stay pending appeal on July 1, 1983. On July 27, 1983, Circuit Justice Blackmun denied EPA's application in an opinion attached as Appendix A infra. This appeal followed.

# THE QUESTION PRESENTED WAS CORRECTLY RESOLVED BY THE DISTRICT COURT

This Court has consistently recognized the importance of trade secrets and of the legal protections afforded this property in our federal system. Aronson v. Quick Point Pencil Co., 440 U.S. 257 (1979); Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470 (1974). Among those protections under state and federal law, the Fifth Amendment serves as a fundamental constraint on the authority of the government to take and destroy private trade secret property. R. Milgrim, 1 Trade Secrets §§ 6.02[10], 6.02A (1982); St. Michael's Convalescent Hospital v. California, 643 F.2d 1369, 1374 (9th Cir. 1981).

The 1978 amendments to FIFRA's disclosure and private use provisions violate the Fifth Amendment by destroying Monsanto's trade secrets and effectively transferring Monsanto's property rights to its business competitors. In so holding, the district court recognized that these far-reaching FIFRA amendments completely reorder established property rights, with devastating consequences for Monsanto and severe implications for continued innovation in producing safer and more effective pesticides. As demonstrated below, the judgment of the district court should be affirmed.

### I. MONSANTO'S TRADE SECRETS ARE CONSTITU-TIONALLY PROTECTED PROPERTY.

The decisions of this Court, the law of trade secrets, and the factual record developed here throughout four years of litigation demonstrate that Monsanto possesses a constitutionally protected property interest in its trade secret research. United States v. General Motors Corp., 323 U.S. 373, 378 (1945); Mountain States Tel. & Tel. Co. v. Dep't Pub. Serv. Reg., 634 P.2d 181, 186 (Mont. 1981). Indeed, it is remarkable that EPA at this late date would suggest otherwise. J.S. 16-17. EPA specifically conceded in the proceedings below that Monsanto does enjoy substantial property rights in its pesticide trade secret information, research and test data. J.S. App. 30a.

The trade secret property in issue here consists of information, research and test data concerning 31 Mon-

FPA places substantial emphasis on the district court's statement that the taking of Monsanto's property in violation of the Fifth Amendment cannot be considered a valid regulation of commerce. J.S. at 10, 14-15; see J.S. App. 33a. Monsanto does not view this as a separate holding that should be central in the determination whether to note probable jurisdiction, and it therefore is not addressed here.

santo products and their appropriate uses. Monsanto has undertaken this confidential research to develop, market, register, and improve its existing pesticide products, both in the United States and abroad. In addition, Monsanto uses these studies to identify potential avenues for further research and to improve its research processes, testing methodology, and chemical synthesis techniques. J.S. App. 21a.

The investment Monsanto must make in developing these trade secrets—which provide the essential basis for the pesticides Monsanto markets—is enormous. At present, Monsanto employs hundreds of chemists, biologists, and other scientists for this purpose, and has spent more than a quarter of a billion dollars since 1960 in developing its pesticides. See Tr. 74-75, 103. Only one in every 10,000 compounds synthesized is finally successful, and the research involved consumes an average of fourteen years between selecting a research target and marketing a product. J.S. App. 5a; Tr. 50. Ultimately, Monsanto's success and survival in the pesticide business depends on those few pesticides developed through this expensive winnowing process that become commercially marketable. Tr. 73-74.8

<sup>\*</sup>Five of Monsanto's registered pesticides account for nearly all of the company's commercial success: Lasso®, Roundup®, Avadex®, Avadex®, BW, and Ramrod®. Tr. 45. Monsanto's annual worldwide pesticide sales exceed \$1 billion. Based on these products, sales by Monsanto Agricultural Products Company, one of Monsanto's four operating companies, accounts for more than 90% of Monsanto's operating income. See Appendix A to Monsanto's Brief in Opposition to Application for Stay Pending Appeal (July 11, 1983) (Affidavit of Dr. Frank S. Serdy) in Ruckelshaus v. Monsanto Co., No. A-1066 (1983).

Monsanto's commercial benefit from this investment in its trade secrets, however, is fundamentally contingent upon maintaining their secrecy and preserving Monsanto's right to exclusive use. Underwater Storage, Inc. v. United States Rubber Co., 371 F.2d 950, 954 (D.C. Cir. 1966), cert. denied, 386 U.S. 911 (1967); see generally R. Milgrim, 1 Trade Secrets §§ 2.03, 7.07[1][a] (1982). The "piggyback" use of these trade secrets on behalf of competitors would eliminate Monsanto's hard-earned innovative advantage without the competitors undertaking the enormous commitment of resources required of Monsanto. See Board of Trade v. Christie Grain & Stock Co., 198 U.S. 236, 250 (1905) (Holmes, J.). Moreover, if competitors had access to Monsanto's trade secret research, it would reveal to them, as it does to Monsanto, each pesticide's chemistry, metabolism, course of degradation, residues, and interactions among ingredients. Tr. 106-09. 117. From this information, competitors could seek to reconstruct Monsanto's product formulas. Tr. 101-02, 192. Furthermore, Monsanto's competitors would gain their own research leads, improve their own research techniques, secure registrations in foreign nations, and even register their competitive products for additional uses in the United States. J.S. App. 23a.

Monsanto therefore preserves the confidentiality of this trade secret information under lock and key, accessible to employees only on a need-to-know basis. Tr. 111. Security guards are employed around the clock, and Monsanto personnel are required to execute confidentiality agreements respecting the information. Complementing these measures, property and tort laws prohibit the unconsented use or disclosure of Monsanto's trade secrets by those to whom they have been revealed in confidence. Sandlin v. Johnson, 141 F.2d 660, 661 (8th Cir. 1944)

(Missouri law); see Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470, 475-77 (1974).

In view of these facts, EPA stipulated at trial that much of the research and test data Monsanto has submitted pursuant to FIFRA "contains or relates to trade secrets as defined by the Restatement of Torts." EPA further stipulated that "Monsanto has certain property rights in its information, research and test data. . . which may be protected by the Fifth Amendment to the Constitution." First Supplemental Stipulation of Facts (Sept. 8, 1980). The district court agreed, resting its holding on the definition of trade secrets set forth in the Restatement of Torts § 757 (1939) and adopted as the law of Missouri.9 Pursuant to that definition, the court found. Monsanto holds "the right to exclude others," "the right to prevent the unauthorized use" of its data to benefit Monsanto's competitors, and "the right to prohibit disclosure of its data." J.S. App. 31a.10

In this Court EPA nevertheless contends that the 1978 FIFRA amendments redefined what is "private property" within the meaning of the Fifth Amendment. EPA acknowledges that while the research remained with Monsanto it constituted trade secrets protected under

<sup>&</sup>lt;sup>9</sup> Monsanto has maintained that federal law also establishes a protected property right in Monsanto's trade secret information, research and test data.

<sup>&</sup>lt;sup>10</sup> EPA is mistaken in suggesting that Monsanto holds these rights for only a limited time under Missouri law. J.S. at 16 n.12. The decision EPA cites, Carboline Co. v. Jarboe, 454 S.W.2d 540, 552-53 (Mo. 1970), actually adopts the "head-start" rule to determine the relief afforded one whose trade secrets have been misappropriated. The rule does not define the property itself, and it is well recognized that trade secrets under Missouri law and elsewhere last into perpetuity if not disclosed or independently reproduced. R. Milgrim, 1 Trade Secrets § 1.01[2] (1982).

state law. J.S. at 16. But according to EPA, once Monsanto submitted its data to the Agency, any "continuing right to confidentiality in the data" somehow became "solely a matter of federal law." Id. at 17. This argument ignores the principle that the Fifth Amendment is as much a part of "federal law" as is federal legislation. Indeed, EPA's argument would emasculate the Taking Clause since, in EPing view, the result of any legislation destroying property ghts would be considered merely a redefinition of "property" rather than a taking. The Framers intended no such result, and this Court has directly rejected EPA's view, holding that the government "does not have unlimited power to redefine property rights." Loretto v. Teleprompter Manhanttan CATV Corp., 102 S. Ct. 3164, 3178 (1982).

For all types of property, an "owner's right to exclude [is] 'one of the most essential sticks in the bundle of rights that are commonly characterized as property.' "Loretto, 102 S. Ct. at 3175 (quoting Kaiser Aetna v. United States, 444 U.S. 164, 176 (1979)). With respect to trade secret property, however, the "right to exclude" is not merely one of the "essential" rights, it is the essential right. See Kewanee Oil Co. v. Bicron Corp., 416 U.S. at 484. Unless the owner of the trade secret can maintain its confidentiality, he has no trade secret property. When the government removes this right to exclude, it has not simply adjusted "Monsanto's right in its property" as EPA claims. J.S. at 21. Instead, it has destroyed the property itself.

Thus, Monsanto's submission of trade secrets in order to register its products is by no means consent to the disclosure and use of that data for its competitors, as EPA seems to suggest. J.S. 16. The fact that Monsanto brought this lawsuit demonstrates as much. Analysis of

the issues here is simply not advanced by EPA's conclusory allegations based on the proposition that Monsanto "voluntarily" submitted its data to EPA and therefore "waived" its Fifth Amendment rights. In addition to the fact that EPA, through its own regulations, agrees that the data were not "voluntarily submitted," it has long been recognized that the "Government cannot make a business dependent upon a permit and make an otherwise unconstitutional requirement a condition to the permit." Standard Airlines, Inc. v. CAB, 177 F.2d 18, 20 (D.C. Cir. 1949). 12

EPA's theory, in fact, recognizes under a different name that the 1978 amendments to FIFRA at issue here do transfer and destroy private property rights under state law, as shown below. This theory certainly provides no basis on which to disturb the conclusion that Monsanto's research and test information is protected property.

### II. THE 1978 AMENDMENTS TO FIFRA TAKE MONSAN-TO'S TRADE SECRET PROPERTY.

This Court's Taking Clause decisions also demonstrate that the drastic 1978 changes to FIFRA result in the taking of Monsanto's trade secret property. EPA's argument to the contrary (J.S. at 18) simply disregards this Court's admonition that a taking depends on the nature of the property involved and a statute's effect on fundamental property rights. E.g., Webb's Fabulous Pharmacies, Inc. v. Beckwith, 449 U.S. 155, 164-65 (1980). As

<sup>&</sup>lt;sup>11</sup> 40 C.F.R. § 2.307(g) (1982) ("no information to which this section applies is voluntarily submitted information").

<sup>&</sup>lt;sup>12</sup> Accord, Loretto v. Teleprompter Manhattan CATV Corp., 102 S. Ct. at 3178 n.17 ("a landlord's ability to rent his property may not be conditioned on his forfeiting the right to compensation for a physical occupation").

the district court found, FIFRA's disclosure and private use provisions appropriate not only the essential "strand," but all of Monsanto's rights in its intangible intellectual property. J.S. App. 31a-33a.

Under FIFRA §§ 10(b) and (d), as amended in 1978, EPA must make private trade secret property relating to pesticide chemistry, metabolism, and testing methodology, among other subjects, "available for disclosure to the public." Indeed, the last sentence of amended FIFRA § 3(c)(2)(A) requires EPA to disclose to the public a manufacturer's submitted information, research and test data within 30 days after approving any pesticide registration. In addition, under amended FIFRA § 3(c)(1)(D), competing producers can obtain pesticide registrations for their competing products by using—despite the owners' objections—trade secret test data previously submitted by competing companies who invested millions of dollars in developing the data. See 7 U.S.C. §§ 136a(c), 136h (1982).

This Court's decisions applying the Taking Clause, particularly with respect to intangible property rights, establish that these FIFRA provisions take Monsanto's trade secret property. The very essence of "property in a trade secret is the power to make use of it to the exclusion of the world." Hartley Pen Co. v. United States District Court, 287 F.2d 324, 328 (9th Cir. 1961) (quoting Cincinnati Bell Foundry Co. v. Dodds, 10 Ohio Dec. Reprint 154 (Super. Ct. 1887) (Taft, C.J.)). See R. Milgrim, 1 Trade Secrets §§ 2.01, 2.05 and 7.07[1][a] (1982). This Court has held in no uncertain terms that "the 'right to exclude,' so universally held to be a fundamental element of the property right, falls within this category of interests that the Government cannot take without compensation." Kaiser Aetna v. United States, 444 U.S. 164,

179-80 (1979). <sup>13</sup> The provisions of FIFRA at issue would make Monsanto's trade secrets available to "the world," destroying this fundamental trade secret right in violation of the firmly-established Fifth Amendment principles recognized in *Kaiser Aetna*. <sup>14</sup>

Moreover, FIFRA's appropriation of Monsanto's trade secrets to afford a "piggyback" or "free ride" to competing pesticide applicants also constitutes a "taking" under settled doctrine. See Loretto v. Teleprompter Manhattan CATV Corp., 102 S. Ct. 3164 (1982) ("taking" found from state transfer of permanent easement from landlords to

<sup>13</sup> See L. Tribe, American Constitutional Law § 9-3 at 460 (1978) (clearest instance of "taking" is where government transfers "the legal powers of enjoyment and exclusion that are typically associated with rights of property"). EPA concedes that FIFRA eliminates Monsanto's right to exclude, but suggests this is not a taking, citing PruneYard Shopping Center v. Robins, 447 U.S. 74 (1980). But PruneYard simply held that the right to exclude must yield to conflicting First Amendment rights, particularly inasmuch as commercial shopping centers derive no economic value from excluding the public. That case has no bearing here, where no First Amendment rights are at stake and loss of the right to exclude with respect to the trade secrets has enormous commercial significance.

<sup>14</sup> Citing Corn Products Refining Co. v. Eddy, 249 U.S. 427, 431-32 (1919), EPA argues that a manufacturer has no constitutional right to sell products without giving the consumer "fair" information about what is being sold. J.S. 20. To the extent EPA is suggesting that the government has constitutional authority to regulate product labeling in order to prevent misbranding—which was the issue in Corn Products—EPA's argument is correct but irrelevant. On the other hand, if EPA means to suggest that the Fifth Amendment places no restraints on the government's taking of trade secrets, EPA's theory flies in the teeth of the cases discussed in the text. Such a theory would obviously read the Taking Clause out of the Constitution, and render meaningless the Fifth Amendment principles that, as EPA itself acknowledges (J.S. 2, 17-18), govern whether a taking occurred.

cable TV companies). A "taking can occur"—as it would under the FIFRA amendments—"simply when the Government by its action... makes it possible for someone else to obtain the use or benefit of another person's property." Aris Gloves, Inc. v. United States, 420 F.2d 1386, 1391 (Ct. Cl. 1970). Provisions such as the FIFRA amendments in issue here, that take one person's property to give to another, present the most "glaring instance" of a "taking" constrained by the Fifth Amendment. Thompson v. Consolidated Gas Utilities Corp., 300 U.S. 55, 79 (1937).

Finally, placing Monsanto's confidential research in the public domain and permitting use for Monsanto's competitors would result in the permanent destruction of Monsanto's trade secret property, for trade secrets once disclosed are forever lost. E.g., Harrington v. National Outdoor Advertising Co., 355 Mo. 524, 196 S.W.2d 786, 791 (1946); see generally R. Milgrim, 1 Trade Secrets §§ 2.03 and 2.05[1] (1982). Trade secret property rights are "not just diminished but obliterated by public disclosure," which is a conclusive "factor pointing toward government disclosures of trade secrets as takings." Indeed, this Court has consistently found that such a destruction of intangible property violates the Taking Clause.

<sup>&</sup>lt;sup>15</sup> Connelly, Secrets and Smokescreens: A Legal and Economic Analysis of Government Disclosures of Business Data, 1981 Wis. L. Rev. 207, 251. See also Note, Constitutional Limitations on Government Disclosure of Private Trade Secret Information, 56 Ind. L.J. 347, 364-68 (1981).

<sup>&</sup>lt;sup>16</sup> See, e.g., Armstrong v. United States, 364 U.S. 40 (1960) (destruction of all property rights in materialmen's liens); Louisville Joint Stock Land Bank v. Radford, 295 U.S. 555 (1935) (elimination of liens in bankruptcy); Pennsylvania Coal Co. v. Mahon, 260 U.S. 393 (1922) (total destruction of mining rights).

EPA attempts to evaluate whether a "taking" results from these FIFRA provisions solely by resort to inapplicable and, in this context, confusing standards such as "physical invasion" and "extent of the interference," while ignoring the standards that properly apply. J.S. at 17-18. For example, EPA's argument that "there is no 'physical invasion' of Monsanto's property" (J.S. 18) is simply irrelevant when intangible intellectual property is in issue, as it is here. This Court, moreover, has explicitly refused to "embrace the proposition that a 'taking' can never occur unless government has transferred physical control." Penn Central Transportation Co. v. New York City, 438 U.S. 104, 123 n.25 (1978).

Likewise, EPA labels the total destruction of Monsanto's property rights a "limited interference" with Monsanto's intellectual property. J.S. at 19. EPA's blithe assertion that Monsanto itself will not be barred from use of the data it will have unwillingly surrendered to the world ignores the nature of trade secret property. J.S. at 19-20. Furthermore, to accept EPA's argument, one would have to believe that despite the Fifth Amendment, the government could freely convert private homes into public shelters so long as it did not evict the present occupants. EPA's related suggestion that taking Mon-

<sup>&</sup>lt;sup>17</sup> In fact, the cases chiefly relied upon by EPA carefully note that there is no "set formula" applicable to all taking situations. Id. at 124; Andrus v. Allard, 444 U.S. 51, 65 (1979) ("[f]ormulas and factors have been developed in a variety of settings").

<sup>&</sup>lt;sup>18</sup> EPA's position is squarely inconsistent with this Court's decisions involving intangible property rights. See, e.g., United States v. Security Industrial Bank, 103 S. Ct. 407, 412 (1982) (survival of physical objects does not alter holding that legal rights of lienholder would be taken); Armstrong v. United States, 364 U.S. 40, 48 (1960) ("liens were destroyed" though physical objects had not "vanished into thin air").

santo's trade secret property is permissible because it may not immediately bankrupt the corporation, given Monsanto's other "competitive advantages," is similarly untenable. J.S. at 19. The occurrence of an unconstitutional taking can hardly depend on the size, resources and entirely separate skills of the persons deprived of their property, nor can it turn on whether they continue to hold other assets. *United States* v. *General Motors Corp.*, 323 U.S. 373, 378 (1945).<sup>19</sup>

For all these reasons, the district court correctly found that FIFRA's permanent destruction of Monsanto's trade secret property rights and conferral of Monsanto's test data on competitors constitutes a "taking" subject to the limitations of the Fifth Amendment.

# III. FIFRA'S TAKING OF MONSANTO'S TRADE SECRET PROPERTY VIOLATES THE FIFTH AMENDMENT'S "PRIVATE USE" LIMITATION.

The district court concluded that the taking of Monsanto's trade secret property pursuant to the 1978 FIFRA

<sup>19 &</sup>quot;[T]he Fifth Amendment concerns itself solely with the 'property'. . . and not with other collateral interests"). Id. EPA's contention that Monsanto has not suffered a taking because Monsanto's confidential formulas are not also required to be disclosed (J.S. at 2, 9, 20-21), is similarly inapposite. Monsanto's trade secrets in its product formulas are distinct from, though related to, the property in issue here. In any event, the disclosures required by FIFRA would make it easier for competitors to identify Monsanto's product formulas by reverse engineering. See page 12 supra. Furthermore, EPA cannot realistically contend that the provision of limited compensation under FIFRA's arbitration scheme in certain instances negates the taking otherwise accomplished by the 1978 amendments. EPA itself concedes that this private compensation/arbitration scheme does not provide just compensation, see page 24 infra. More fundamentally, the payment of compensation confirms-not refutes-that a taking has occurred.

amendments violates the Fifth Amendment's Taking Clause on two independent grounds. First, the 1978 amendments to the disclosure and private use provisions take Monsanto's property to further a "private use," which the Fifth Amendment forbids regardless of the compensation paid. J.S. App. 31a-32a. Thompson v. Consolidated Gas Utilities Corp., 300 U.S. 55 (1937). Second, Monsanto's trade secret property is taken without "just compensation." J.S. App. 34a-36a.

Both the scheme of the 1978 FIFRA amendments and their legislative history demonstrate that the extraordinary transfer of Monsanto's trade secret property to its business rivals constitutes a forbidden taking for predominantly "private use." Indeed, EPA barely contends otherwise. J.S. 22. The direct effect of the 1978 amendments is to permit Monsanto's competitors to obtain FIFRA registrations by using Monsanto's trade secret property. 7 U.S.C. § 136a (c)(1)(D) (1982); J.S. App. 30a, 32a. Recognizing this effect, Congress enacted a special compensation/arbitration scheme that requires the private companies benefiting from Monsanto's property to pay Monsanto under certain circumstances for their use of its trade secrets. Congress expressly characterized this type of provision as conferring a "free ride" to

<sup>&</sup>lt;sup>20</sup> EPA's contention that these provisions serve a sufficient public purpose to be sustained as an exercise of Congress' power under the Commerce Clause, see J.S. at 14-15, does not pardon this violation of the Fifth Amendment. It has long been established that the Fifth Amendment is an independent limitation on Congress' substantive authority under the commerce power. Kaiser Aetna v. United States, 444 U.S. 164, 174 (1979); United States v. Cress, 243 U.S. 316, 326 (1917).

private competitors on the "substantial testing expense . . . borne by the first applicant."21

The private use and disclosure provisions in the 1978 amendments to FIFRA, on their face, thus present an unparallelled violation of the proscription against taking property for a predominantly "private use." This Court has never sanctioned coercing innocent persons to surrender their property to competitors who have not "contributed in money, services, negotiations, skill, forethought or otherwise" to its development. Thompson v. Consolidated Gas Utilities Corp., 300 U.S. 55, 78 (1937); Washington-Summers, Inc. v. Charleston, 430 F. Supp. 1013, 1015 (S.D.W. Va. 1977) ("property cannot be taken . . . for a predominantly private purpose.").

"'[T]he question of what is a public use is a judicial one.'" TVA v. Welch, 327 U.S. 546, 552 (1946) (quoting Cincinnati v. Vester, 281 U.S. 439, 446 (1930)). EPA suggested in the district court that despite the predominantly private use resulting from this property transfer, the provisions could be upheld as a means of

<sup>&</sup>lt;sup>21</sup> S. Rep. No. 92-8382, (Part II) at 72-73 (1972) (discussing this possibility during consideration of the 1972 amendments). See also Hearings, 93d Cong., 1st Sess. at 11-12 (1973). EPA's own public pronouncements outside this litigation have shared this assessment, describing the statutory disclosure and use provisions as conferring an "unconsented free ride" upon Monsanto's competitors. Pest. Reg. Notice 83-4 at p. 8 (1983).

<sup>&</sup>lt;sup>22</sup> Accord, Connelly, Secrets and Smokescreens: A Legal and Economic Analysis of Government Disclosure of Business Data, 1981 Wis. L. Rev. 207, 249 ("[A]ny disclosure of a trade secret that smacked of a property transfer from one private party to another would likely be held to contravene the fifth amendment, without regard to any question of compensation"). See also Missouri Pac. Ry. Co. v. Nebraska, 164 U.S. 403 (1896).

promoting competition. The district court properly rejected this theoretical justification in view of the actual operation of the provisions. As numerous commentators have agreed, the Taking Clause requires judicial consideration of the statute's actual effect, not merely the theoretical purpose EPA suggests the property transfer might serve. Consistent with these principles and the predominantly private use to be made by competitors of Monsanto's trade secrets, the district court correctly found that the 1978 trade secret disclosure and use provisions take private property in violation of the Fifth Amendment.

# IV. "JUST COMPENSATION" IS NOT PROVIDED FOR THE TAKING OF MONSANTO'S TRADE SECRET PROPERTY.

Even if the taking of Monsanto's trade secret property were not unconstitutional as a "private use," the 1978 FIFRA amendments contravene the Fifth Amendment's prohibition against taking property "without just compensation." In the district court, EPA maintained that either FIFRA's private compensation/arbitration scheme or the Tucker Act, 28 U.S.C. § 1491 (1976 & Supp. V 1981), would meet the constitutional requirement for providing just compensation. The district court concluded otherwise. The court correctly found on the basis of the factual record and FIFRA's legislative histo-

Epstein, Not Deference, But Doctrine: The Eminent Domain Clause, 1982 Sup. Ct. Rev. 351, 365-69; Note, Public Use, Private Use, and Judicial Review in Eminent Domain, 58 N.Y.U.L. Rev. 409 (1983); Note, Eminent Domain: Private Corporations and the Public Use Limitation, 11 U. Balt. L. Rev. 310 (1982); Meidinger, The "Public Uses" of Eminent Domain, 11 Envtl. L. 1, 44-49 (1980). See also B. Ackerman, Private Property and the Constitution 190 n.5 (1977).

ry that the FIFRA arbitration scheme did not satisfy the Fifth Amendment requirements articulated by this Court and that Congress had withdrawn any supposed Tucker Act remedy. J.S. App. 34a-36a.

EPA now concedes in its jurisdictional statement that FIFRA's private compensation/arbitration scheme cannot constitutionally suffice as a means of "just compensation." J.S. 23-24, 25. In an attempt to recharacterize the district court's decision, however, EPA proposes that this Court hear argument on a different issue—whether FIFRA's arbitration scheme is constitutional apart from its adequacy as a means of providing "just compensation." J.S. 24-26. Yet this separate and distinct constitutional issue was not decided by the district court and need not be considered as a ground for appeal. J.S. App. 34a-35a.

<sup>&</sup>lt;sup>24</sup> Monsanto contended and the district court held that the FIFRA private compensation/arbitration scheme fails to satisfy the special constitutional requirements for providing "just compensation" under the Fifth Amendment. This Court has held that the ascertainment of "just compensation" is inherently a judicial inquiry that not even Congress can assume. See, e.g., United States v. New River Collieries Co., 262 U.S. 341, 343-44 (1923). The FIFRA arbitration procedure violates this constitutional stricture and due process by delegating the task to a non-Article III decisionmaker, without establishing any standards for compensation, while precluding judicial review. Northern Pipeline Construction Co. v. Marathon Pipe Line Co., 102 S. Ct. 2858 (1982); Pacemaker Diagnostic Clinic of America, Inc. v. Instromedix, Inc., 52 U.S. L.W. 2105 (9th Cir. Aug. 5, 1983). See also Crowell v. Benson, 285 U.S. 22 (1932).

Therefore, the more general and abstract issue addressed by EPA—divorced from the constitutionality of the arbitration scheme as a means of providing just compensation—was not decided by the district court. In the event probable jurisdiction is noted, Monsanto will brief instead the merits of the issue actually decided by the district court regarding the FIFRA private compensation/arbitration scheme.

Similarly, EPA's suggestion that this recharacterized issue may not be "ripe" for judicial review, J.S. 24-25, is irrelevant and inapplicable to the "just compensation" issues that are appropriately raised on this appeal.<sup>25</sup>

The sole "just compensation" issue raised by the jurisdictional statement, therefore, is whether the district court was correct in finding that no compensation whatsoever is available under the Tucker Act for FIFRA's taking of Monsanto's trade secret property. In deciding this issue, the district court closely followed the test articulated by this Court in the Regional Rail Reorganization Act Cases, 419 U.S. 102, 126 (1974). Specifically, the court concluded that as part of the 1978 FIFRA amendments, "Congress has 'withdrawn the Tucker Act grant of jurisdiction to the Court of Claims to hear a suit involving the (challenged statute) founded . . . upon the Constitution.' "J.S. App. 35a (quoting 419 U.S. at 126)."

<sup>\*\*</sup>See note 24 supra. This Court firmly established in the Regional Rail Reorganization Act Cases, 419 U.S. 102, 123-125 (1974), that the arbitration issue actually decided by the district court—the availability and adequacy of a mechanism to provide just compensation for a threatened taking—"is ripe for adjudication" in this context. Id. at 123.

<sup>&</sup>lt;sup>26</sup> Monsanto argued in the district court that regardless whether Congress had withdrawn the Tucker Act remedy, the taking required by the 1978 amendments to FIFRA violated the due process requirement that takings be effected in judicial proceedings. J.S. App. 33a-34a. In addition, Monsanto argued that the comprehensive taking required by the amendments rendered the taking constitutionally "unauthorized," thereby rendering the statutory provisions themselves invalid and warranting injunctive relief. See, e.g., Louisville Joint Stock Land Bank v. Radford, 295 U.S. 555 (1935) (destruction of liens by bankruptcy act enjoined). Should this Court note probable jurisdiction, Monsanto will renew these independent arguments in support of the judgment.

Both the structure of the amended FIFRA and its legislative history amply support the district court's finding that Congress intended FIFRA's own private compensation/arbitration scheme to be the exclusive means of providing "just compensation" for the taking of trade secret property. By requiring the competitors profiting from use of Monsanto's property to offer compensation under this scheme, Congress unmistakably intended that private parties themselves must pay for the taking, not the United States and the public at large.

Similarly, Congress directed that any property owner such as Monsanto who declines to participate in this private compensation/arbitration scheme "shall forfeit the right to compensation for the use of the data in support of the application." Section 3(c)(1)(D)(ii), 7 U.S.C. § 136a(c) (1)(D)(ii) (1982). Congress' decision to make the specified procedure exclusive, and avoid judicial involvement under the Tucker Act in providing "just compensation," is further reflected in its withdrawal of judicial review of the private arbitration decisions. Id. Indeed, the principal Senate sponsor of the 1978 amendments specifically described this private compensation/arbitration scheme as Congress' intended means of providing "just compensation" for the taking effected by FIFRA. 123 Cong. Rec. S13095 (July 29, 1977) (Sen. Leahy).

EPA's jurisdictional statement reveals little basis for disagreement with the district court's conclusion that any Tucker Act remedy has been withdrawn. Certainly the single fact that Congress had permitted resort to the Tucker Act in the Regional Rail Reorganization Act of 1970 does not demonstrate that Congress followed the same course in the 1978 FIFRA amendments, as EPA seems to imply. J.S. 22-24. Moreover, EPA is mistaken in suggesting that other courts have upheld the availability

of "just compensation" under the Tucker Act for takings by FIFRA.

The district court identified several additional factors indicating that the Tucker Act remedy had been withdrawn or was inadequate, such as the necessity for property owners to file an endless stream of suits and the exposure of the Treasury to multi-million dollar claims by thousands of pesticide producers. J.S. App. 36a. Even if limitations on the form and conditions for relief under the Tucker Act would permit the Court of Claims to grant "just compensation" for the taking of trade secret property in this manner, the magnitude of such an oppressive burden on the Treasury and the Court of Claims confirms that Congress intended to make FIFRA's private compensation/arbitration scheme exclusive.

In sum, FIFRA's taking of Monsanto's trade secret property is "without just compensation" and violates the Fifth Amendment, and the district court correctly so ruled.

<sup>&</sup>lt;sup>27</sup> In one of the cases cited by EPA for this proposition, Union Carbide Agricultural Products Co. v. Costle, 632 F.2d 1014 (2d Cir. 1980), cert. denied, 450 U.S. 996 (1981), far from finding that the remedy was available, the court treated the question as being wholly unresolved. 632 F.2d at 1019. Similarly, while the district court in Chevron Chemical Co. v. Costle, 499 F. Supp. 732, 742-43 (D. Del. 1980), offered the view that Tucker Act relief might be available, the court of appeals reviewing that decision expressly declined to resolve the issue. 641 F.2d 104, 117 (3d Cir.), cert. denied, 452 U.S. 961 (1981).

### CONCLUSION

The judgment of the district court should be affirmed.

Respectfully submitted.

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Dated: September 12, 1983



### Appendix A

### IN THE SUPREME COURT OF THE UNITED STATES

No. A-1066

WILLIAM D. RUCKELSHAUS, ADMINISTRATOR, UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

V.

MONSANTO COMPANY

ON APPLICATION FOR STAY

[July 27, 1983]

JUSTICE BLACKMUN, Circuit Justice.

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. § 136 et seq., as amended in 1978, 92 Stat. 820, requires pesticide manufacturers to register their products with the Environmental Protection Agency (EPA) prior to marketing them in the United States. The EPA decides whether to register a pesticide; it bases its decision on an evaluation of test data concerning the product's effectiveness and potential dangers. This data typically is submitted by the pesticide's manufacturer. Section 3(c)(1)(D) of FIFRA. 7 U.S.C. § 136a(c)(1)(D) (1976 ed., Supp. V), provides, however, that test data submitted in connection with a particular pesticide may be used by manufacturers seeking registration of similar pesticides. In effect, a subsequent applicant for registration may "piggyback" its registration on the efforts of the initial applicant. The subsequent applicant must offer to compensate the initial applicant, and compensation is to be determined by binding arbitration if the parties cannot agree on a sum. § 3(c)(1)(D), 7 U.S.C. § 136(c)(1)(D) (1976 ed., Supp. V). In addition, health and safety data submitted by the initial applicant may be disclosed to the public pursuant to § 10(d), 7 U.S.C. § 136h(d) (1976 ed., Supp. V).

Respondent Monsanto Company manufactures several registered pesticides. To obtain registration, Monsanto submitted test data developed at a cost claimed to be in excess of \$23 million. These test data are trade secrets under the law of Missouri, and Monsanto consequently has the right to prevent their use and disclosure. Monsanto brought suit in the United States District Court for the Eastern District of Missouri. contending that the use or disclosure of its test data pursuant to the FIFRA provisions described above would constitute an unconstitutional taking of its property. The District Court agreed, and enjoined enforcement of these and related provisions of FIFRA. The District Court declined to stay its injunction pending direct appeal to this Court, and the Administrator of the EPA has applied to me for a stay. Having reviewed the application, the response, and the other memoranda and supporting documents filed by the parties and several amici, I deny the application.

A Justice of this Court will grant a stay pending appeal only under extraordinary circumstances, Graves v. Barnes, 405 U.S. 1201, 1203 (1972) (POWELL, J., in chambers), and a district court's conclusion that a stay is unwarranted is entitled to considerable deference. Id., at 1203-1204; Bateman v. Arizona, 429 U.S. 1302, 1304 (1976) (REHNQUIST, J., in chambers). An applicant for a stay "must meet a heavy burden of showing not only that the judgment of the lower court was erroneous on the merits, but also that the applicant will suffer irreparable injury if the judgment is not stayed pending his appeal." Whalen v. Roe, 423 U.S. 1313, 1316 (1975) (MARSHALL, J., in chambers); see Graves v. Barnes, 405 U.S., at 1203. An applicant's likelihood of success on the merits need not be considered, however, if the applicant fails to show irreparable injury from the denial of the stay. Whalen v. Roe, 423 U.S., at 1317-1318.

In this case, the Administrator has not convinced me that irreparable harm will result if the District Court's injunction remains in effect pending appeal. During this interim period, the injunction prevents the EPA from registering new pesti-

cides through use of previously submitted test data, and members of the public will be unable to obtain test data relating to health and safety. The EPA will remain able, however, to register new pesticides; applicants for registration may submit their own test data to support their applications, and may rely on previously submitted data if the submitters have given permission. The EPA has adopted interim procedures to permit registration in this manner. See 48 Fed. Reg. 32012-32013 (1983). If an applicant for registration chooses to rely on previously submitted data without the submitter's permission, the EPA may process the application although it may not actually register the product pending appeal. While registrations and disclosures will be delayed somewhat, "delay alone is not, on these facts, irreparable injury." Whalen v. Roe, 423 U.S., at 1317.

Two other considerations enter into my decision to deny this application. First, the granting of a stay might well cause irreparable harm to Monsanto. If the District Court's injunction were lifted, the EPA would be free to use Monsanto's trade secrets for the benefit of its competitors and could disclose them to members of the public. Monsanto's trade secrets would become public knowledge, and could not be made secret again if the judgment below ultimately is affirmed. In addition, the Administrator has not been particularly expeditious in seeking a stay or in pressing his appeal. This application was filed more than 7 weeks after the District Court issued its amended judgment. The Administrator has requested and received a 30-day extension of time in which to file his jurisdictional statement with this Court. While certainly not dispositive, the Administrator's failure to act with greater dispatch tends to blunt his claim of urgency and counsels against the grant of a stay. See Beame v. Friends of the Earth, 434 U.S. 1310, 1313 (1977) (MARSHALL, J., in chambers).

I shall enter an order accordingly.

No. 83-196

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ALEXANDER L. STEVAS.

# In the Supreme Court of the United States

OCTOBER TERM, 1983

WILLIAM D. RUCKELSHAUS, ADMINISTRATOR, UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, APPELLANT

ν.

### MONSANTO COMPANY

ON APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF MISSOURI

#### REPLY MEMORANDUM FOR THE APPELLANT

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### TABLE OF AUTHORITIES

			Pa	ge
Cases:				
Berman v. Parker, 348 U.S. 26				3
Bowman Transportation, Inc. v. Arkansas- Freight System, 419 U.S. 281				3
Hodel v. Indiana, 452 U.S. 314				3
Hodel v. Virginia Surface Mining and Reclamation Association, 452 U.S. 264.	• •			3
National Parks and Conservation Association Morton, 498 F.2d 765				5
Penn Central Transportation Co. v. New York, 438 U.S. 104				3
Webb's Fabulous Pharmacies, Inc. v. Beckv 449 U.S. 155		-		4
Constitution, statutes and regulations:				
U.S. Const. Amend. V				4
7 U.S.C. 136a(c)				2
7 U.S.C. 136h(d)				2
7 U.S.C. 136h(g)				2
40 C.F.R. :				
§ 2.201(i)				5

	Page	-
Mis	cellaneous:	
	H.R. Rep. 95-663, 95th Cong., 1st Sess. (1977)	
	Restatement of Torts (1939) 4	,
	S. Rep. 92-838, 92d Cong., 2d Sess., Pt. II (1972)	
	S. Rep. 92-970, 92d Cong., 2d Sess. (1972) 3	
	S. Rep. 95-334, 95th Cong., 1st Sess. (1977)	

## In the Supreme Court of the United States

OCTOBER TERM, 1983

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WILLIAM D. RUCKELSHAUS, ADMINISTRATOR, UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, APPELLANT

v.

#### MONSANTO COMPANY

ON APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF MISSOURI

## REPLY MEMORANDUM FOR THE APPELLANT

Monsanto asks this Court summarily to affirm the judgment below. It is evident, however, that the various constitutional holdings of the district court cannot be reconciled with the decisions of this Court; and it is equally obvious that a decision striking down substantial portions of a major regulatory statute as unconstitutional warrants plenary review by this Court.

1. Despite Monsanto's effort to cast the 1978 amendments to FIFRA as a broad destruction of its "trade secret" property rights without just compensation, the statute's effects are far more limited than Monsanto suggests.

First, the provisions at issue do not "eliminate Monsanto's hard-earned innovative advantage" (Mot. to Aff. 12). Rather, as we explained in the Jurisdictional Statement (at 18-20), they establish procedures for limited use and disclosure by EPA of only health and safety data (see J.S. 3

& n.2). The data consideration provisions involve disclosure to no one; they simply permit EPA to refer to the original submitter's data when reviewing subsequent applications for the same or similar pesticides. 7 U.S.C. 136a(c). Even then, the exclusive use and compensation periods may afford additional protection to the original data submitter (see J.S. 7-8). The disclosure provisions expressly prohibit disclosure of information that could reveal "manufacturing or quality control processes" or certain details pertaining to "deliberately added" inert ingredients unless "the Administrator has first determined that disclosure is necessary to protect against an unreasonable risk of injury to health or the environment."7 U.S.C. 136h(d). The original submitter is further protected by the prohibition against disclosure to foreign or multinational pesticide producers, unless the original applicant has consented. 7 U.S.C. 136h(g). Taken as a whole, the statutory scheme creates a carefully circumscribed procedure that ensures the innovative incentives of "head start" protection by limiting disclosure in ways that Congress deemed sufficient for that purpose. Accordingly, Monsanto's concern (Mot. to Aff. 12) that the statute would "eliminate" its "hard-earned innovative advantage" is unfounded.

Second, Monsanto's argument ignores the countervailing public health concerns Congress sought to promote. In both 1972 and 1978, Congress clearly stated that the data consideration and compensation provisions were enacted to achieve an efficient registration system and to prevent the monopoly effects that would be created if the data submitter retained de facto control over the use of the data. S. Rep.

<sup>&</sup>lt;sup>1</sup>The district court stated (J.S. App. 21a) that while the data submitted in support of a pesticide application may serve other corporate objectives, Monsanto generates this data "primarily for registration purposes."

95-334, 95th Cong., 1st Sess. 3, 7-8, 30-31 (1977); H.R. Rep. 95-663, 95th Cong., 1st Sess. 18, 41, 42 (1977); S. Rep. 92-970, 92d Cong., 2d Sess. 12 (1972); S. Rep. 92-838, 92d Cong., 2d Sess., Pt. II, at 69, 72-73 (1972). Congress also determined that the public interest in minimizing the environmental hazards of pesticides would be served by disclosure of the specified safety and health data. S. Rep. 95-334, supra, at 4, 13; H.R. Rep. 95-663, supra, at 18-19, 42. It was entirely proper for Congress to exercise its power to regulate interstate commerce to achieve these objectives. See, e.g., Hodel v. Virginia Surface Mining and Reclamation Association, 452 U.S. 264, 282 (1981); Bowman Transportation, Inc. v. Arkansas-Best Freight System, 419 U.S. 281, 298 (1974). Monsanto asserts (Mot. to Aff. 22-23) that the desire to promote competition is merely a "theoretical" justification and that the benefits accorded to its competitors constitute an impermissible private use. This contention is, as we have described, unfounded. In any event, this Court has clearly held that the judiciary should not substitute its judgment for congressional assessment of the public need or wisdom of benefitting private parties to further the public welfare. Hodel v. Indiana, 452 U.S. 314, 326 (1981); Berman v. Parker, 348 U.S. 26, 32-34 (1954).

2. Monsanto is also incorrect in asserting that FIFRA's data consideration and disclosure provisions constitute a taking of its property. As we have explained (J.S. 17-22), this Court has held that in analyzing whether a taking has occurred one must look to "the character of the [governmental] action and \* \* \* the nature and extent of the interference with rights in the [property] as a whole." Penn Central Transportation Co. v. New York City, 438 U.S. 104, 130-131 (1978). Here, as we have shown, the limited interference involved arises from a "public program adjusting the benefits and burdens of economic life to promote the common good" (id. at 124), and this fact, ignored by Monsanto, weighs heavily against the conclusion of a taking.

Indeed, the decision on which Monsanto relies (Mot. to Aff. 15), Webb's Fabulous Pharmacies, Inc. v. Beckwith, 449 U.S. 155 (1980), is consonant with our position (id. at 163):

This Court has been permissive in upholding governmental action that may deny the property owner of some beneficial use of his property or that may restrict the owner's full exploitation of the property, if such public action is justified as promoting the general welfare. See, e.g., Andrus v. Allard, 444 U.S., at 64-68; Penn Central Transportation Co. v. New York City, 438 U.S., at 125-129.[2]

- 3. Several additional points in Monsanto's submission invite brief response.
- a. Monsanto mistakenly relies (Mot. to Aff. 13) on a stipulation in this case regarding the classification of its data as trade secrets within the Restatement of Torts (1939) definition. The purpose of the stipulation was to avoid protracted litigation over the characterization of the data under that definition. While the stipulation discusses property rights, it does not concede that Monsanto's interests in the data at issue are protected as property under the Fifth Amendment. Instead, the stipulation merely states that such protection "may" exist. Whether it does is one of the questions presented for review.

<sup>&</sup>lt;sup>2</sup>The Court's conclusion in Webb's Fabulous Pharmacies that a taking had occurred in the "narrow circumstances" of that case (449 U.S. at 164) does not undercut the more general principles recited above. Indeed, the Court expressly reserved the question whether the same practice it proscribed in Webb's would be constitutional in another context. Id. at 165.

b. Similarly misplaced is Monsanto's reliance (Mot. to Aff. 15 & n.11) on EPA regulations governing disclosure under the Freedom of Information Act. 40 C.F.R. 2.201(i). 2.208, 2.307(g). See National Parks and Conservation Association v. Morton, 498 F.2d 765, 770 (D.C. Cir. 1974). That data submitted under FIFRA are not considered to be "voluntarily submitted" for FOIA purposes does not answer the constitutional questions here presented. The FOIA regulations do not change the fact that Monsanto chose to seek registration of its pesticides and acted on its decision by submitting the health and safety data at issue here. Just as an applicant for a patent chooses to make the necessary disclosures in order to obtain the benefits of exclusive use. so too does a pesticide registrant choose to reveal to the government certain information in exchange for the commercially valuable authorization to sell its product.

For these reasons and those stated in the Jurisdictional Statement, probable jurisdiction should be noted.

Respectfully submitted.

REX E. LEE Solicitor General

**OCTOBER 1983** 

DOJ-1983-10

DEC 21 1983

ALEXANDER L. STEVAS,

## In the Supreme Court of the United States

OCTOBER TERM, 1983

WILLIAM D. RUCKELSHAUS, ADMINISTRATOR, UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, APPELLANT

v.

#### MONSANTO COMPANY

ON APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF MISSOURI

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### QUESTIONS PRESENTED

1. Whether Section 3(c)(1)(D) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136a(c)(1)(D) (which permits applicants to cite and EPA to consider in support of subsequent applications by other companies, health and safety data that were submitted to the government in support of initial applications for pesticide registration), works an unconstitutional taking of property requiring issuance of injunctive relief.

2. Whether Sections 3(c)(2)(A) and 10 of FIFRA, 7 U.S.C. 136a(c)(2)(A) and 7 U.S.C. 136h (which require EPA to disclose publicly health and safety data submitted to the agency in support of a pesticide registration application), are beyond Congress's power and constitute an unconstitutional taking of property war-

ranting injunctive relief.

3. Whether the constitutionality of the arbitration scheme established in Section 3(c) (1) (D) (ii) of FIFRA, 7 U.S.C. 136a(c) (1) (D) (ii) (which provides that an original submitter of data or an applicant who cited that data may initiate binding arbitration if the parties fail to agree on the amount of compensation) is ripe for review, and, if so, whether the arbitration provision denies due process or amounts to an unconstitutional delegation of judicial power.

## TABLE OF CONTENTS

		Page
Opini	on below	1
Juriso	liction	1
Const	itutional and statutory provisions involved	2
State	ment	2
1.	Statutory and regulatory background	3
2.	The 1972 Amendments	6
3.	The 1978 Amendments	11
4.	The proceedings below	14
Sumn	nary of argument	16
Argur	ment:	
I.	FIFRA's data consideration and disclosure provisions are plainly within the authority of Congress to regulate interstate commerce	19
	A. The data consideration provisions	21
	B. The data disclosure provisions	24
II.	FIFRA's data consideration and disclosure provisions do not take property in violation of the Fifth Amendment	26
	A. An interest in preserving the exclusive use and secrecy of health and safety data re- quired under FIFRA does not qualify as property protected by the Taking Clause of the Fifth Amendment	26
	B. Even if Monsanto does possess a protected property right in its test data, the 1978 Amendments are not a taking of that interest	33
	1. The data consideration provisions	34
	2. The data disclosure provisions	37

Argur	ment—Continued:	Page
III.	Even if FIFRA's data consideration and disclosure provisions take Monsanto's property, the district court erred in granting injunctive relief	40
IV.	The constitutional challenges to the arbitration and compensation scheme are not ripe for resolution and in any event are without merit	44
	A. The district court erred in considering Mon- santo's constitutional attacks on the arbitra- tion and compensation scheme in Section 3(c)(1)(D)(ii)	44
	B. Neither the Due Process Clause nor Article III requires invalidation of the arbitration and compensation scheme	47
Conclu	usion	50
	TABLE OF AUTHORITIES	
Cases	:	
A	Abbott Laboratories v. Gardner, 387 U.S. 136 Agins v. City of Tiburon, 447 U.S. 255	45 33
	Supp. 124, remanded, 529 F.2d 1297	8
A	Indrews v. Louisville & N. R.R., 406 U.S. 320	47
A	Andrus V. Allard, 444 U.S. 51	37, 40
_	442 U.S. 289	
	Berman v. Parker, 348 U.S. 26	24
В	Sowman Transp., Inc. v. Arkansas-Best Freight	90 99
C	System, Inc., 419 U.S. 281	20, 23
	1024	11
C	Chevron Chemical Co. v. Costle, 499 F. Supp. 732, aff'd, 641 F.2d 104, cert. denied, 452 U.S. 9618, 31, 34,	11, 28, 41, 44

C

ases—Continued:	Page
Chrysler Corp. v. Brown, 441 U.S. 281	28
Corn Products Refining Co. v. Eddy, 249 U.S. 427	
Crane v. Hahlo, 258 U.S. 142	47
Dow Chemical Corp. v. Costle, 464 F. Supp. 395	41
Dow Chemical Corp. v. Train, 423 F. Supp. 1359	42
Duke Power Co. v. Carolina Environmental Study	
	41, 45
E.I. Du Pont de Nemours Powder Co. v. Masland, 244 U.S. 100	29
Edwards v. St. Louis-S. F. R.R., 361 F.2d 946	48
EPA v. California, 426 U.S. 200	28
Federal Security Administrator V. Quaker Oats	
Co., 318 U.S. 218	39
FCC v. Schreiber, 381 U.S. 279	26,38
FTC v. Standard Oil Co., 449 U.S. 232	47
Goldblatt v. Hempstead, 369 U.S. 590	34
Hancock v. Train, 426 U.S. 167	27, 28
Hardware Dealers Mutual Fire Insurance Co. v. Glidden Co., 284 U.S. 151	47
Hines v. Davidowitz, 312 U.S. 52	27
Hodel v. Indiana, 452 U.S. 31420, 24,	
Hodel v. Virginia Surface Mining & Reclamation	
Ass'n, 452 U.S. 264	20, 23
Hurley V. Kincaid, 285 U.S. 95	44
Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470	27, 29
Larson V. Domestic & Foreign Commerce Corp.,	
337 U.S. 682	41
Ludwig Honold Mfg. Co. v. Fletcher, 405 F.2d	
1123	48
Miller v. Schoene, 276 U.S. 272	34
Mobay Chemical Corp. v. Costle, 12 Env't Rep.	
Cas. (BNA) 1572, appeal dismissed, 439 U.S.	
320	10
Mobay Chemical Corp. v. Costle, 447 F. Supp. 811	11
Mobay Chemical Corp. v. Costle, 517 F. Supp. 252	
and 517 F. Supp. 254, aff'd, 682 F.2d 419, cert.	
denied, No. 82-241 (Nov. 8, 1982)8,	
Mulford v. Smith, 307 U.S. 38	20

Cases—Continued:	Page
National Fertilizer Association v. Bradley, 301	07.00
U.S. 178	25, 39
Pipeline Co., 458 U.S. 50	49
U.S. 197	20
Penn Central Transp. Co. v. New York City, 438 U.S. 104	33, 36
Pennsylvania Coal Co. v. Mahon, 260 U.S. 393	
Pennsylvania v. ICC, 525 F.2d 91	43
	34
July 23, 1982)	34
PPG Industries, Inc. v. Stauffer Chemical Co.,	
C.A. No. 83-1941 (D.D.C. filed July 7, 1983)	47
Pruneyard Shopping Center v. Robins, 447 U.S.	
74	35-36
Regional Rail Reorganization Act Cases, 419 U.S.	
10241, 43,	44, 45
Reichelderfer v. Quinn, 287 U.S. 315	
Sandlin v. Johnson, 141 F.2d 660	27
South Carolina v. Katzenbach, 383 U.S. 301	49
Switchmen's Union v. National Mediation Board,	
320 U.S. 297	48, 49
Toilet Goods Association v. Gardner, 387 U.S. 158.	45, 46
Union Carbide Agricultural Products Co. v. Costle,	
632 F.2d 1014, cert. denied, 450 U.S. 996	34, 41
Union Carbide Agricultural Products Co. v. Ruck-	40
elshaus, 571 F. Supp. 117	49
United States v. Causby, 328 U.S. 256	42
United States v. Central Eureka Mining Co., 357	0.4
U.S. 155	34
United States v. County of Allegheny, 322 U.S.	00
174	28
United States v. Darby, 312 U.S. 100 United States v. Georgia Public Service Commis-	20, 23
sion, 371 U.S. 285	28
Utah Fuel Co. v. National Bituminous Coal	20
Comm'n, 306 U.S. 56	96 99
Comm n, 900 U.S. 90	20,00

Cases—Continued	Page
Webb's Fabulous Pharmacies, Inc. v. Becks 449 U.S. 155	U.S. 31
Constitution, statutes, regulations and rule:	
U.S. Const.:	
Art. I, § 8, Cl. 13 (Commerce Clause)1 Art. III	6, 47, 48, 49 passim
Due Process Clause	
Clean Air Act, 42 U.S.C. (Supp. V) 7607(a) ( Federal Food, Drug, and Cosmetic Act, 21 U (& Supp. V) 301 et seq.:	
21 U.S.C. 331(a)	5
21 U.S.C. 342(a)	
21 U.S.C. 342(a) (2) (B)	
21 U.S.C. 346a	5
21 U.S.C. 346a(a)	
21 U.S.C. 355(a)	
21 U.S.C. 355(b)	
21 U.S.C. 355(j)	
21 U.S.C. 360(f)	
21 U.S.C. 360(j)	20
21 U.S.C. 379	21
Federal Insecticide, Fungicide and Rodent Act of 1947, ch. 125, 61 Stat. 163 et seq.:	icide
§ 2(u) (2) (c), 61 Stat. 165	
§ 2(u) (2) (d), 61 Stat. 165	
§ 2(u) (2) (g), 61 Stat. 165	
§ 3, 61 Stat. 166	4
§ 3(a) (1), 61 Stat. 166	4
§ 3(a) (3), 61 Stat. 166	
§ 3(a) (5), 61 Stat. 166 § 3(c) (4), 61 Stat. 167	
§ 4(a), 61 Stat. 167	
8 4(h) 61 Stat 167	

Constitution, statutes, regulations	
and hule—Continued:	Page
§ 4(c), 61 Stat. 168	4
§ 8(b), 61 Stat. 170	4
§ 8(c), 61 Stat. 170	5
Federal Insecticide Act of 1910, ch. 191, 36 Stat.	4
Federal Insecticide, Fungicide, and Rodenticide	
Act of 1978, 7 U.S.C. 136 et seq	2, 11
§ 2(u), 7 U.S.C. 136(u)	4
§ 2(bb), 7 U.S.C. 136(bb)	2, 26
§ 3, 7 U.S.C. 136a	
§ 3(a), 7 U.S.C. 136a(a)	2
§ 3(a) (1) (D), 7 U.S.C. 136a(a) (1) (D)	40
§ 3(b), 7 U.S.C. 136a(b)	25
§ 3(c) (1) (D), 7 U.S.C. 136a(c) (1) (D)	passim
§ 3(c) (1) (D) (i), 7 U.S.C. 136a(c) (1) (D)	
(i)	12
§ 3(c) (1) (D) (ii), 7 U.S.C. 136a(c) (1) (D)	
(ii)12, 13, 15, 19,	44, 49
§ 3(c) (1) (D) (iii), 7 U.S.C. 136a(c) (1) (D)	
(iii)	13
§ 3(c) (2) (A), 7 U.S.C. 136a(c) (2) (A)3, 13,	
§ 3(c) (5), 7 U.S.C. 136a(c) (5)	26 2
§ 3(c) (5) (C), 7 U.S.C. 136a(c) (5) (C) § 3(c) (5) (D), 7 U.S.C. 136a(c) (5) (D)	2
§ 3(c) (7), 7 U.S.C. 136a(c) (7)	26
§ 6(d), 7 U.S.C. 136d(d)	25
§ 10, 7 U.S.C. 136h	
§ 10(b), 7 U.S.C. 136h(b)	
§ 10(d), 7 U.S.C. 136h(d)	
§ 10(d)(1), 7 U.S.C. 136h(d)(1)	13
§ 10(d) (1) (A), 7 U.S.C. 136h(d) (1) (A)	37
§ 10(d)(1)(B), 7 U.S.C. 136h(d)(1)(B)	37
§ 10(d)(1)(C), 7 U.S.C. 136h(d)(1)(C)	37
§ 10(g), 7 U.S.C. 136h(g)	14, 37
§ 30, 7 U.S.C. 136x	49
Federal Water Pollution Control Act, 33 U.S.C.	
1318(b)	40
Hart-Scott-Rodino-Antitrust Improvements Act of	
1976, 15 U.S.C. 18a	21
Railway Labor Act, 45 U.S.C. 153 First (i)	47

Constitution, statutes, regulations	•
and rule—Continued:	Page
Safe Drinking Water Act, 42 U.S.C. 300j-4(d)	40
Toxic Substances Control Act, 15 U.S.C. 2613(b)	40
Trade Secrets Act, 18 U.S.C. 1905	
Tucker Act, 28 U.S.C. 1491	19, 41
Pub. L. No. 86-139, § 2, 73 Stat. 286	
Pub. L. No. 88-305, § 2, 78 Stat. 190	6
Pub. L. No. 92-516, 86 Stat. 973 et seq.:	
§ 3, 86 Stat. 979	6, 9
§ 3(c) (1) (D), 86 Stat. 979	10, 11
§ 3(c) (5) (C)-(D), 86 Stat. 980-981	
§ 3(d) (1), 86 Stat. 981	6
§ 3(d) (1) (C), 86 Stat. 981	
§ 4, 86 Stat. 983	
§ 6, 86 Stat. 984	
§ 7, 86 Stat. 987	
§ 9, 86 Stat. 988	7
§ 10, 86 Stat. 989	
§ 12, 86 Stat. 989	
§ 12(2)(G), 86 Stat. 990	
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p. 40061	9
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23,	24, 48

## In the Supreme Court of the United States

OCTOBER TERM, 1983

No. 83-196

WILLIAM D. RUCKELSHAUS, ADMINISTRATOR, UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, APPELLANT

v.

### MONSANTO COMPANY

ON APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF MISSOURI

### BRIEF FOR THE APPELLANT

#### OPINION BELOW

The opinion of the district court (J.S. App. 1a-37a) is reported at 564 F. Supp. 552.

## JURISDICTION

The judgment of the district court (J.S. App. 39a-40a) was entered on April 12, 1983. An amended judgment (J.S. App. 41a-43a) was entered on May 9, 1983. The Administrator of the Environmental Protection Agency filed a notice of appeal to this Court on May 10, 1983 (J.S. App. 44a-46a). On July 1, 1983, Justice Blackmun extended the time for docketing the appeal to August 8, 1983. The Jurisdictional Statement was filed on August 5, 1983, and the Court noted probable jurisdiction on October 11, 1983 (J.A. 260). The jurisdiction of this Court rests on 28 U.S.C. 1252.

# CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

The Fifth Amendment to the United States Constitution and the relevant portions of the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. 136 et seq., are reprinted at J.S. App. 47a-57a.

#### STATEMENT

The court below declared unconstitutional several important provisions of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 et seq., the federal legislation regulating the marketing and use of pesticides. As we will show, in enacting FIFRA Congress struck a measured balance between the need for increased competition and the need for innovation in the pesticide industry. In accomplishing these objectives, the statute also accommodates private industry's interest in protecting information and the public's interest in understanding the potential hazards of pesticide products.

Under FIFRA, persons seeking to market a pesticide product in the United States first must obtain a registration for the product from the Environmental Protection Agency (EPA). 7 U.S.C. 136a(a). Before issuing the registration, the Administrator of EPA must determine, inter alia, that the pesticide's use will not cause unreasonable adverse effects on the environment, taking into account the benefits as well as the risk to humans or the environment. 7 U.S.C. 136(bb), 136a(c)(5)(C)-(D). The Administrator bases this determination in part on test data submitted or cited by the applicant for registration, data that generally include information on the chemical nature and structure of the pesticide as well as test results on the potential dangers of the product.

<sup>&</sup>lt;sup>1</sup> The health and safety data required for registration consist of the following major types of studies: (1) acute toxicity studies, which define how poisonous the pesticide is when ingested, inhaled, or applied to the skin or eyes; (2) chronic toxicity studies, which are used to determine if chronic exposure to the pesticide

The provisions struck down by the district court were designed to permit EPA to consider the health and safety data submitted by one applicant in support of the application of another company (the "data consideration provisions), 7 U.S.C. 136a(c)(1)(D); they also require EPA to disclose these data to qualifying members of the public (the "data disclosure" provisions), 7 U.S.C. 136a(c)(2)(A), 136h(b) and (d). This case, therefore, relates only to health and safety data; the case does not involve a company's confidential product formulas or manufacturing processes, which are protected from disclosure by the terms of the statute (7 U.S.C. 136h(d)). Moreover, the protections afforded by FIFRA are wholly distinct from rights to exclusivity that a company may enjoy under the patent laws.

## 1. Statutory and regulatory background

The past century has witnessed the transformation of American agriculture into a large-scale industry characterized by intensive cultivation of the land. A major factor in this change, as well as a contributor to marked improvements in productivity, has been the widespread use of pesticides to control weeds and crop damage caused by insects, disease and animals. See S. Rep. 92-838, 92d Cong., 2d Sess. 3-4, 6-7 (1972). Greater use of pesticides has brought not only the benefit of protecting crops and ensuring high yields, but also the risk of harm to humans and the environment. The recognition of this hazard has been reflected in federal regulation of pesticide use for nearly 75 years. In 1910, Congress passed the Federal

will have any long-term health effects such as causing cancer or birth defects; (3) residue studies, which describe the level of the pesticide and its degradation products which remain in food products; (4) environmental chemistry studies, which are used to determine how much of the pesticide and its degradation products remain in the environment after application; and (5) fish and wildlife studies, which define how toxic the pesticide is to fish and wildlife which may be exposed to the pesticide after application in the environment. See J.S. App. 17a; 47 Fed. Reg. 53192-53221 (1982).

Insecticide Act, which made it unlawful to manufacture and sell insecticides that were adulterated or misbranded as defined by the statute. Ch. 191, 36 Stat. 331. The following decades brought dramatic growth in pesticide research and development, and the states began to regulate pesticides extensively, leading to the adoption in 1946 of a model state statute, the uniform Insecticide, Fungicide and Rodenticide Act. S. Rep. 92-838, supra, at 7; H.R. Rep. 313, 80th Cong., 1st Sess. 3 (1947).<sup>2</sup> These developments led to the enactment in 1947 of the more comprehensive Federal Insecticide, Fungicide, and Rodenticide Act. Ch. 125, § 3, 61 Stat. 166.

In order to assume greater control over the marketing and use of pesticides, the 1947 legislation provided for the registration of pesticides marketed in the United States. H.R. Rep. 313, supra, at 2-3. The Act required applicants for registration to submit to the Secretary of Agriculture certain information regarding the pesticide, including the label bearing the directions for use and the claims made for the product, and, "if requested by the Secretary," any test data underlying the claims on the label. § 4(a), 61 Stat. 167.<sup>3</sup> The legislation set general standards for the labeling of pesticide products, including a requirement for a poison label for substances acutely

<sup>&</sup>lt;sup>2</sup> The use of pesticides also became widespread in nonagricultural contexts. For example, pesticides, as defined by FIFRA (7 U.S.C. 136(u)), include household insecticides, lawn and garden pesticides, swimming pool chemicals, industrial pesticides, termite treatments, and fumigants.

<sup>&</sup>lt;sup>3</sup> Section 3(a)(1) of the statute made it illegal to market an unregistered pesticide in interstate commerce. 61 Stat. 166. While the Secretary could initially refuse a registration by notifying an applicant that the application did not comply with the substantive requirements of the law, the applicant could then force the issuance of a registration merely by filing a protest ("protest registration"). § 4(c), 61 Stat. 168. In such a case, however, a registrant was subject to increased penalties for any subsequent conviction for offenses relating to matters about which the Secretary had warned the registrant. § 8(b), 61 Stat. 170.

toxic to humans and a requirement for directions and warnings that were judged to be necessary and adequate to protect the public and to prevent injury to humans, other animals and vegetation.  $\S\S 2(u)(2)(c)$  and (d), 3(a)(3), 61 Stat. 165, 166. A product whose label did not meet these requirements was classified as misbranded and could not legally be sold in interstate commerce.  $\S 3(a)(5)$ , 61 Stat. 166.4

Thus, the 1947 legislation was primarily a licensing and labeling statute. The application for registration could include test data, although for many years only a limited amount of such data was required (J.S. App. 25a; J.A. 219-221). In addition, the Secretary of Agriculture was authorized to require the submission of a pesticide's formula, if he deemed it necessary. § 4(b), 61 Stat. 167. The 1947 Act specifically prohibited disclosure of "any information relative to formulas of products" (§§ 3(c) (4), 8(c), 61 Stat. 167, 170), but did not address the disclosure of health and safety data. Nor did it address the possible consideration of such data by agency officials in processing a subsequent application for the same pesticide.

Mounting public concern over the long-term effects of pesticides led to further regulation. In 1954, Congress amended the Federal Food, Drug, and Cosmetic Act to regulate pesticide residues in food products. 21 U.S.C. 346a. Under these provisions no food products can be marketed legally if pesticide residues exceed established tolerances. 21 U.S.C. 331(a), 342(a)(2)(B) and 346a (a). Persons seeking to establish a tolerance must submit data disclosing, inter alia, the name, chemical iden-

<sup>&#</sup>x27;In addition to these categories of misbranding, Congress declared a product misbranded if it was an insecticide, fungicide or herbicide that would be injurious to humans, other animals or vegetation "when used as directed or in accordance with commonly recognized practice." § 2(u) (2) (g), 61 Stat. 165-166.

<sup>&</sup>lt;sup>5</sup> As a matter of practice, however, the Department of Agriculture did not publicly disclose any of this information.

tity and composition of the pesticide chemical, as well as reports on its safety. 21 U.S.C. 346a(d)(1).

In 1959, Congress amended FIFRA to extend regulation to new classes of substances that had come into common use: nematocides, defoliants, dessicants and plant regulators (Pub. L. No. 86-139, § 2, 73 Stat. 286). And in 1964, acting on the recommendation of a Presidential Scientific Advisory Committee, Congress eliminated "protest registration," see n.3, supra, providing instead for administrative and judicial review of a decision to refuse or cancel a registration for a pesticide found to be unsafe (Pub. L. No. 88-305, § 2, 78 Stat. 190; see S. Rep. 92-838, supra, at 8-9). In 1970, the Department of Agriculture's FIFRA responsibilities were transferred to the new Environmental Protection Agency. Reorganization Plan No. 3 of 1970, 35 Fed. Reg. 15623 (1970). These various changes were not sufficient to satisfy the increasing public concern, however, and in 1972 Congress enacted extensive changes in the regulatory scheme.

## 2. The 1972 Amendments

The comprehensive revision of FIFRA by Congress in 1972 included a number of measures to provide increased environmental protection. For the first time, the statute regulated the use of pesticides directly, as well as their labeling and marketing. Congress extended the reach of the legislation to include pesticides made and sold within a single state (§§ 3, 12, 86 Stat. 979, 989-990) and added new provisions for review, cancellation and suspension of registrations (§ 6, 86 Stat. 984). These amendments also

<sup>&</sup>lt;sup>6</sup> Pursuant to Section 12(2)(G) of the amended Act, it was unlawful to use a pesticide contrary to its labeling. 86 Stat. 990. In addition, the Administrator was authorized to register a pesticide for restricted use only. Section 3(d)(1), 86 Stat. 981. Under certain circumstances, application of a restricted use pesticide was required to be directed by persons certified as applicators under the statute.  $\frac{8}{3}$  3(d)(1)(C), 4, 86 Stat. 981, 983.

<sup>&</sup>lt;sup>7</sup> The statute also upgraded the enforcement mechanisms by requiring registration of pesticide-producing establishments and

supplied a new substantive criterion for registration, that the pesticide would not cause "unreasonable adverse effects on the environment" (§ 3(c)(5)(C)-(D), 86 Stat. 980-981).

In addition, Congress revamped the registration procedures and addressed the issues of consideration and disclosure of submitted data, which had generated considerable controversy. For many years after the passage of the 1947 Act, the Department of Agriculture required only limited health and safety data. J.S. App. 25a; J.A. 219-221. Advances in scientific knowledge and analytical techniques, however, led to more stringent requirements. In 1971, the pesticide industry told Congress that increasingly rigorous administrative criteria for registration had required them to submit more extensive, and costly, safety and health data. Federal Pesticide Control Act of 1971: Hearings Before the House Comm, on Agriculture, 92d Cong., 1st Sess, 331 (1971). See Def't Exh. DDD at 60. The Department of Agriculture (and later EPA) adopted the practice of considering data submitted by one company when reviewing subsequent applications by others for registration of the same or a similar pesticide. This practice was well known to the companies involved. During congressional consideration of the 1972 Amendments, the industry's trade association, the National Agricultural Chemicals Association (NACA), acknowledged that (Federal Environmental Pesticide Control Act: Hearings Before the Subcomm. on Agricultural Research and General Legislation of the Senate Comm. on Agriculture and Forestry, 92d Cong., 2d Sess., Pt. II, 245 (1972)):

Under the present law registration information submitted to the Administrator has not routinely been made available for public inspection. Such informa-

authorizing their inspection (§§ 7, 9, 86 Stat. 987, 988); by authorizing stop sale, use or removal orders for pesticides in violation of the Act (§ 13, 86 Stat. 991) and by providing for civil penalties in addition to criminal enforcement (§ 14, 86 Stat. 992).

tion has, however, as a matter of practice but without statutory authority, been considered by the Administrator to support the registration of the same or a similar product by another registrant. [8]

In the industry's view, this practice, coupled with proposals for public disclosure of health and safety data, would have had a negative effect on research and development. NACA asked Congress to create proprietary rights in the data in the form of a statutory right to exclusive use of the data for the purpose of registration. Federal Pesticide Control Act of 1971: Hearings Before the House

<sup>8</sup> See J.A. 70-74. Although the court below found that the Department of Agriculture had a policy against considering data developed by one company to support another company's registration (J.S. App. 26a), this finding cannot undermine the basis upon which Congress legislated in 1972. Moreover, the evidence in this case refutes this finding. Testimony by employees who processed applications for registration established that they routinely depended on the knowledge that sufficient health and safety data had been generated to support a prior registration when they approved a subsequent application for the same or a similar chemical (J.A. 219-227, 228-230, 234-245). Indeed, the Department of Agriculture even published a list of those pesticides that would require no additional toxicological data for registration. The purpose of this publication, "Interpretation 18," was to facilitate subsequent registrations (J.A. 236-237, 240). The only contrary evidence in this case came from the prior testimony of two former Department of Agriculture officials. But that testimony was not only directly contradicted by that of Harold Alford, who was employed as an Assistant Director of the USDA Registration Division (J.A. 98-101), it also was rejected by the court in which it was originally introduced. See Mobay Chemical Corp. v. Costle, 517 F. Supp. 252 and 517 F. Supp. 254, 267 n.11 (W.D. Pa. 1981), aff'd, 682 F.2d 419 (3d Cir.), cert. denied, No. 82-241 (Nov. 8, 1982). The district court in Mobay, as well as every court (other than the court below) that has considered the matter, concluded that all previously submitted data were regarded by the Department of Agriculture and EPA as available for approving subsequent applications. Chevron Chemical Co. v. Costle, 641 F.2d 104, 109 (3d Cir.), cert. denied, 452 U.S. 961 (1981); Amchem Products, Inc. v. GAF Corp., 391 F. Supp. 124, 128 (N.D. Ga. 1975), remanded 529 F.2d 1297 (5th Cir. 1976). Accordingly, the district court's contrary finding should be rejected as clearly erroneous.

Comm. on Agriculture, supra, at 331; J.A. 70-74, 81-82. The House passed such a restriction (H.R. 10729, 92d Cong., 1st Sess. § 3(c)(2)(D) (1971), over the objection of several Members that it was an unwarranted extension of patent protection and generally anticompetitive. H.R. Rep. 92-511, 92d Cong., 1st Sess. 69 (remarks of Rep. Foley), 72 (remarks of Rep. Dow) (1971); 117 Cong. Rec. 39978, 40034, 40061 (1971).

The Senate bill, as reported by the Senate Committee on Agriculture and Forestry, retained the exclusive use provision because the committee thought proprietary rights would encourage research. S. Rep. 92-838, supra, at 6. Other Senators strongly objected to the new proposal. They believed this change in the registration process would require wasteful duplication of testing and raise barriers to entry into the pesticide market that exceeded the protection provided by the patent laws. S. Rep. 92-970, 92d Cong., 2d Sess. 12 (1972). The Senate Committee on Commerce, to whom the bill was also referred, struck the exclusive use provision; this action was supported by the Department of Justice and EPA. Id. at 2, 12-13; S. Rep. 92-838 (Pt. II), 92d Cong., 2d Sess. 21 (1972).

This conflict in the Senate was resolved by a compromise that was intended to provide both an incentive for research and a means for maintaining entry of competitors into the market. S. Rep. 92-838. Pt. II. supra. at 69, 71-73. The two committees decided on a mandatory data licensing scheme under which EPA could consider studies submitted by one company in support of the application of another firm, so long as the second company offered to compensate the original data submitter. Id. at 71-73. The amount of compensation would be determined either through negotiation between the parties, or, if that failed, by EPA order subject to judicial review. Pub. L. No. 92-516, § 3, 86 Stat. 979. The compromise was accepted by the full Senate and acceded to by the House during the conference. H.R. Conf. Rep. 92-1540, 92d Cong., 2d Sess. 9, 31 (1972).

At the same time, Congress added a new Section 10 (86 Stat. 989) to govern public disclosure of data submitted in support of applications for registration. This provision allowed applicants to designate portions of submitted data as "trade secrets or commercial or financial information" and it prohibited EPA from publicly disclosing such information. Moreover, the data consideration provision (§ 3(c)(1)(D)) provided that any "trade secret" data that could not be publicly disclosed under Section 10 could not be considered by EPA at all to support another registration application, unless the original submitter consented. 86 Stat. 979. Thus, the data consideration/mandatory licensing scheme would apply only to data that fell outside the scope of "trade secret" protection under Section 10.

The 1972 Amendments, however, failed to define "trade secrets," and failed to specify an effective date. The latter question was resolved in 1975 when Congress amended Section 3(c)(1)(D) to provide that the mandatory licensing provisions applied only to data submitted on or after January 1, 1970. Pub. L. No. 94-140, 89 Stat. 751. The definition of "trade secrets" was left to the EPA Administrator and the courts.

EPA maintained that in the 1972 and 1975 Amendments Congress had intended to give trade secret protection to only a narrow range of information—principally statements of formulas and manufacturing processes—that did not include health and safety data. Such data, therefore, could be disclosed to the public and could be

<sup>&</sup>lt;sup>9</sup> Section 3(c) (1) (D), as amended in 1975, was challenged by an original data submitter on the ground that Section 3(c) (1) (D) caused an unconstitutional taking of its property rights in the data it had submitted prior to January 1, 1970. This claim was rejected by a three-judge court, which held that Section 3(c) (1) (D) did not "take" any property rights. Mobay Chemical Corp. v. Costle, 12 Env't Rep. Cas. (BNA) 1572 (W.D. Mo. 1978). A direct appeal to this Court under 28 U.S.C. 1253 was dismissed on the ground that the three-judge court had been improperly convened. 439 U.S. 320 (1979).

considered by EPA in support of registration applications. In a series of lawsuits, data-submitting firms challenged EPA's interpretations and obtained several decisions holding that the "trade secret" prohibition in the 1972 Act applied to any data, including health and safety data, that met the expansive definition of "trade secret" set forth in the Restatement of Torts § 757 (1939). E.g., Chevron Chemical Co. v. Costle, 443 F. Supp. 1024 (N.D. Cal. 1978); Mobay Chemical Corp. v. Costle, 447 F. Supp. 811 (W.D. Mo. 1978). As a result of these decisions, the "trade secret" prohibition in Section 10 operated to bar public access to much of the data on which EPA based its decisions to register pesticides and the corresponding prohibition in Section 3(c) (1) (D) allowed data-submitters to prevent any other firm from obtaining registrations for products that were the same or substantially similar to previously registered products unless the second firm duplicated the data supporting the first registration, or it was determined, after perhaps years of litigation, that particular items were not trade secrets. In part because of such "trade secret" controversies, "the process of registering new pesticides simply ground to a halt." Chevron Chemical Co. v. Costle, 499 F. Supp. 732 (D. Del. 1980), aff'd on other grounds, 641 F.2d 104, 111 (3d Cir.), cert. denied, 452 U.S. 961 (1981).10 See H.R. Rep. 95-663, 95th Cong., 1st Sess. 18 (1977); S. Rep. 95-334, 95th Cong., 1st Sess. 3 (1977).

#### 3. The 1978 Amendments

Faced with this breakdown in the registration program, Congress, in the Federal Pesticide Act of 1978 (1978 Amendments) (7 U.S.C. 136 et seq.), comprehensively revised the FIFRA data consideration and disclosure provisions. The 1978 Amendments abolished the

<sup>&</sup>lt;sup>10</sup> See generally, Schulberg, The Proposed FIFRA Amendments of 1977: Untangling the Knot of Pesticide Registration, 2 Harv. Envtl. L. Rev. 342 (1977).

1972 prohibition on agency consideration of "trade secret" data because it had operated to discourage small potential competitors from entering the market by requiring them to duplicate health and safety tests for products similar to those already registered. Congress was concerned that FIFRA, in practice, acted as a defacto extension of patents beyond the statutory period of protection. See, e.g., S. Rep. 95-334, supra, at 8, 30-31.

In order to promote competition and eliminate needless duplicative testing of pesticide chemicals like those already registered (see S. Rep. 95-334, supra, at 30-31), Congress established a new registration scheme. The costs of developing health and safety data are now spread among all beneficiaries of the data; at the same time, innovation incentives are provided by exclusive use and compensation provisions that are independent of whatever protections a company may have under the patent laws (ibid.). Under the 1978 Amendments, applicants are granted a 10-year period of exclusive use for data on new active ingredients contained in pesticides registered after September 30, 1978. § 3(c)(1)(D)(i), 7 U.S.C. 136a(c)(1)(D)(i). All other data submitted after December 31, 1969, may be cited and considered in support of another application for 15 years following the original submission, if the applicant offers to compensate the original submitter. § 3(c)(1)(D)(ii), 7 U.S.C. 136a(c)(1)(D)(ii). In these instances, the data are not disclosed to the latter applicant but are viewed only by

<sup>&</sup>lt;sup>11</sup> Most of the pesticide products for which registration is sought contain active ingredients that are also contained in previously registered products. Because the first registrant(s) of products containing a particular active ingredient normally will have supplied substantial amounts of health and safety data, EPA's files contain much data relevant to subsequent decisions whether to register other products containing the same ingredient. As the district court found, most of the testing and research is done by a few, relatively large firms, of which Monsanto is one (J.S. App. 4a).

EPA personnel.<sup>12</sup> The later applicant, in order to cite the data, must offer to compensate the original submitter; if the parties cannot agree on the amount of compensation, either may initiate binding arbitration proceedings.<sup>13</sup> Data that do not qualify for either the 10-year period of exclusive use or the 15-year period of compensation may be considered by EPA without limitation. § 3(c) (1) (D) (ii), 7 U.S.C. 136a(c) (1) (D) (iii). All of these provisions operate independently of the patent laws, so chemicals or products that are patented by the original data submitter may not be copied by other companies for 17 years (35 U.S.C. Supp. V) 154). Thus, the data consideration provisions come into play only when the chemical or product is not patentable or when patent protection has expired.

The 1978 Amendments also added a new provision, Section 10(d) (7 U.S.C. 136h(d)), that provides for disclosure of all health and safety data to qualified requesters.<sup>14</sup> This provision was designed to enable members of

<sup>&</sup>lt;sup>12</sup> The later applicant need not have, and usually will not have, obtained or seen a copy of the original submitter's data in order to cite the data in support of the application. EPA makes public lists of persons who have submitted data along with general descriptions of the information. Applicants may use these lists to determine what data to cite.

 $<sup>^{13}</sup>$  The decisions of the arbitrator may be overturned for "fraud, misrepresentation, or other misconduct." 7 U.S.C. 136a(c)(1)(D)(ii).

<sup>&</sup>lt;sup>14</sup> While Section 3(c) (2) (A) also requires the Administrator to make registration data available to the public, that Section is subject to Section 10, which specifically provides for the disclosure of the data at issue in this case. See 7 U.S.C. 136a(c) (2) (A), 136h(d) (1). For the purposes of this brief, references to Section 10 shall be deemed to include Section 3(c) (2) (A) as well. Under Section 10(d) (1), 7 U.S.C. 136h(d) (1), EPA must, on request, disclose to qualified requestors "[a]ll information concerning the objectives, methodology, results, or significance of any test or experiment performed on or with a registered or previously registered pesticide or its separate ingredients, impurities, or degradation products, and any information concerning the effects of

the public to assess for themselves the hazards posed by pesticide products and to participate in and evaluate EPA's registration decisions. See, e.g., H.R. Rep. 95-663, 95th Cong., 1st Sess, 18 (1977); 123 Cong. Rec. 25711 (1977) (remarks of Sen. Kennedy). The same Section, however, prohibits EPA from disclosing information that would reveal "manufacturing or quality control processes" or certain details pertaining to "deliberately added" inert ingredients unless "the Administrator has first determined that disclosure is necessary to protect against an unreasonable risk of injury to health or the environment." In addition, Section 10(g), 7 U.S.C. 136h (g), generally prohibits EPA from disclosing data to representatives of foreign or multinational pesticide companies, unless the original submitter consents. § 10(g). 7 U.S.C. 136h (g).15

## 4. The proceedings below

In its complaint in this case (J.A. 15-28), Monsanto sought injunctive and declaratory relief from the operation of the data consideration provisions of Section 3(c) (1)(D), 7 U.S.C. 136a(c)(1)(D), and the disclosure provisions of Section 10, 7 U.S.C. 136h, and related Section 3(c)(2)(A), 7 U.S.C. 136a(c)(2)(A). Monsanto alleged that the data consideration provision, Section 3(c)(1)(D), constitutes a "taking" of property for a private purpose without just compensation, in violation of the Fifth Amendment, and that the data disclosure provisions, Sections 3(c)(2)(A) and 10, are beyond Congress's Commerce Clause powers and effectuate a taking

such pesticide on any organisms or the behavior of such pesticides in the environment, including, but not limited to, data on safety to fish and wildlife, humans and other mammals, plants, animals, and soil, and studies on persistence, translocation, and fate in the environment, and metabolism."

<sup>&</sup>lt;sup>15</sup> Most, if not all, of the major pesticide companies are multinational and therefore are precluded by this Section from obtaining such data. J.A. 208; J.S. App. 4a.

without just compensation in violation of the Fifth Amendment. The complaint further alleged that the arbitration scheme provided by Section 3(c)(1)(D)(ii) violates the company's due process rights and constitutes

an unconstitutional delegation of judicial power.

Following a bench trial, the district court ruled in favor of Monsanto. The court concluded that the data consideration and disclosure provisions of FIFRA are beyond Congress's Commerce Clause powers and constitute an unconstitutional taking of property in violation of the Fifth Amendment. The court held that Monsanto has a state-protected property right (based on the trade secret definition in the Restatement of Torts § 757 (1939)) in the data it submits to EPA, which precludes EPA from considering Monsanto's data in support of another person's registration application or from disclosing the data publicly. Section 3(c)(1)(D), the court concluded, appropriates Monsanto's "fundamental right \* \* to exclude" others from use of its property, furthers private rather than public purposes, and operates as an unconstitutional taking of Monsanto's property (J.S. App. 31a-32a). The court also found that FIFRA's disclosure provisions (§§ 3(c)(2)(A) and 10) "effectively destroy" Monsanto's property, adding that disclosure is "beyond Congress' regulatory powers" because the public interest is satisfied by EPA's analysis of the pesticide's hazards and by the labeling requirements under FIFRA (J.S. App. 32a-33a). The court further concluded that Congress had withdrawn the Tucker Act remedy, which would ordinarily provide Monsanto with "just compensation," on the ground that the compensation and exclusive use provisions of Section 3 (7 U.S.C. 136a) "were intended to be the sole compensation for any taking" (J.S. App. 35a). Finally, the court held (id. at 34a) that the data-compensation scheme established in Section 3 is unconstitutional because it does not provide "just compensation" and because it denies Monsanto "due process" and amounts to an unconstitutional delegation of

judicial power. The court recognized (J.S. App. 36a-37a) that every other court that had considered these issues had held FIFRA constitutional, but chose not to follow those decisions.

The district court enjoined EPA from implementing "in any manner, directly or indirectly," FIFRA Sections 3(c) (1) (D) and (2) (A), 10(b) and (d) (J.S. App 40a). In addition, it specifically enjoined "any use or consideration of or disclosure to any other person of any of [Monsanto's] information, research and test data, whenever submitted \* \* \* unless [EPA] shall have first [Monsanto's] express written permission" (ibid.). Both EPA and Monsanto moved to amend the judgment. EPA sought to clarify that the judgment did not preclude release of Monsanto's health and safety data to other agencies of the federal government or to Congress. EPA also moved for a stay pending appeal to this Court. Monsanto asked the court to add a new paragraph to the judgment specifying that EPA could process registrations for those manufacturers that can generate their own data or obtain the data from another manufacturer. On May 9, 1983, the district court issued an amended judgment that accommodated both EPA's and Monsanto's requests for amendment but denied EPA's motion for a stay (J.S. App. 41a-43a). EPA's subsequent motion in this Court for a stay pending appeal was denied. No. A-1066 (July 27, 1983) (Blackmun, Circuit Justice).

## SUMMARY OF ARGUMENT

I. The statutory provisions that permit EPA to consider previously submitted data in reviewing later pesticide applications were enacted as part of a carefully crafted scheme designed to achieve two principal objectives: to assure the safety and efficacy of potentially hazardous pesticides and to promote competition in the industry. Since the time and expense involved in performing the requisite health and safety tests could act as a

barrier to entry, discouraging less affluent firms from reaching the market. Congress struck a legislative balance. While the predicate testing remains essential to the initial approval of a pesticide, it was deemed unnecessary to require these tests to be duplicated for subsequent registrations of products with the same or similar composition. In this way, the need to preserve public health and safety standards was accommodated with the desire to avoid the adverse economic impact of forcing potential competitors to reinvent the wheel for each product. At the same time. Congress afforded some incentives for innovators. First, the innovator retains the protection of the patent laws where applicable: his invention may not be copied for 17 years, Second, FIFRA provides a period of exclusive use and a scheme of compensation for original data submitters, so that certain information cannot be relied upon by potential competitors for 10 years and when such reliance is available the innovator may be compensated for his testing expenses.

Substantial public policies similarly underlie the data disclosure provisions. While confidential product formulas and manufacturing practices cannot be disclosed, FIFRA allows qualified members of the public to obtain certain health and safety data. Such disclosure may not be made to representatives of multinational companies, a restriction that bars access to most, if not all, of Monsanto's competitors in the research and development of pesticides (J.S. App. 21a). The disclosure that is permitted allows interested members of the public to participate in the agency decisionmaking process and affords the opportunity to assess in a meaningful way the risks attendant upon pesticide use.

In light of the public purposes advanced by this regulatory scheme, the district court erred in concluding that these provisions of FIFRA exceed Congress's power under the Commerce Clause to regulate the pesticide industry.

II. A. The district court was also incorrect in ruling that FIFRA's data consideration and disclosure provi-

sions constitute a taking of property in violation of the Fifth Amendment. Although it correctly determined that Monsanto did not possess a federally-created property interest in its health and safety data, the court nevertheless found that such a right existed under Missouri law. The court's analysis is flawed. First, the court failed to recognize that whatever rights Monsanto held prior to the time it submitted data to EPA, those rights became subject to the federal regulatory scheme when Monsanto chose to make its submissions in order to obtain commercially valuable pesticide registrations. Second, because the challenged provisions are part of a comprehensive and uniform federal scheme regulating the use of data submitted pursuant to that scheme, state laws are preempted to the extent that they are in irreconcilable conflict with the functioning of that scheme. And, even if state law continues to govern, the court misconstrued the limited protection afforded by state trade secrecy law.

Accordingly, Monsanto retained no cognizable property interest under the Fifth Amendment in the health and safety data it submitted to EPA, and that is dispositive

of its Fifth Amendment claim.

B. Even if it is determined that Monsanto retained a protected property interest, FIFRA does not cause a "taking" of property within the meaning of the Fifth Amendment. When the nature of the government action, and the strong public policies it fosters, is weighed against the limited impact on Monsanto (which retains significant rights and benefits), it is clear that no taking has occurred. Monsanto's assertions boil down to nothing more than unilateral expectations of competitive advantage flowing from the federal regulatory scheme itself. This provides no foundation for a taking claim.

III. Since, in our view, no taking has occurred, the Court need not reach Monsanto's remaining contentions. But even if FIFRA is deemed to cause a taking of property, the district erred in granting injunctive relief. Where, as here, EPA's actions are authorized by statute

and serve an important public purpose, the only remaining issue relating to the availability of injunctive relief is whether just compensation will be provided. While FIFRA affords Monsanto a measure of compensation from private parties who seek to rely on the data consideration provisions in obtaining "me-too" registrations, a claim against the government for just compensation remains available under the Tucker Act, 28 U.S.C. 1491, since Congress evinced no intent to withdraw that remedy. The district court's conclusion to the contrary is incorrect.

IV. The district court should not have entertained Monsanto's attack on the arbitration and compensation scheme in Section 3(c)(1)(D)(ii). This issue is not ripe for adjudication because Monsanto has not yet been involved in the arbitration process. Thus, the question is hypothetical at this point and any disposition would be merely advisory. Should Monsanto later have occasion to proceed through the arbitration scheme, and should it be dissatisfied with the result, it could seek judicial relief.

In any event, the arbitration and compensation scheme fully satisfies the standards established by this Court, and thus offends neither the Due Process Clause nor Article III. Indeed, it is quite similar to other adjudicatory mechanisms this Court has upheld for the determination of statutorily-created rights.

## ARGUMENT

I. FIFRA'S DATA CONSIDERATION AND DISCLO-SURE PROVISIONS ARE PLAINLY WITHIN THE AUTHORITY OF CONGRESS TO REGULATE IN-TERSTATE COMMERCE

Although the district court acknowledged that Congress's purpose in enacting the data consideration and disclosure provisions was to promote competition in the marketplace and to vindicate the public's right to information about the harmful effects of pesticide products (J.S. App. 13a-14a, 17a), the court incorrectly concluded that these statutory provisions were beyond the authority

conferred on Congress by the Commerce Clause of the Constitution (J.S. App. 32a-34a, 39a). The court did not, and could not, hold the pesticide industry immune from congressional regulation on the ground that it does not engage in or affect interstate commerce. Rather, the court simply disagreed with Congress's policy judgment that the particular statutory provisions at issue serve the public interest. But it is Congress, rather than the courts, that is empowered by the Commerce Clause to determine what regulation of the manufacture and use of pesticides will promote the public health and welfare.

It is, for example, long established that Congress may properly act "to prevent the flow of commerce from working harm to the people of the nation." Mulford v. Smith, 307 U.S. 38, 48 (1939). And this Court has held on many occasions that there need only be some rational basis for congressional action in order to sustain an exercise of the plenary authority granted to Congress by the Commerce Clause. See, e.g., United States v. Darby, 312 U.S. 100, 121 (1941). More particularly, this Court has consistently upheld, as authorized by the commerce power, federal legislation regulating business competition or activities causing potential environmental damage, the two primary purposes served by the statutory provisions at issue here. Hodel v. Indiana, 452 U.S. 314, 329 (1981); Hodel v. Virginia Surface Mining & Reclamation Ass'n, 452 U.S. 264, 282 (1981); Bowman Transp., Inc. v. Arkansas-Best Freight System, Inc., 419 U.S. 281, 298 (1974): Northern Securities Co. v. United States. 193 U.S. 197, 337-338 (1904).

Nor is it unusual for Congress to require, as a condition of participating in commerce, that persons supply information to federal agencies that they might otherwise choose not to disclose. For example, firms seeking to sell securities to the public (15 U.S.C. 77aa, 77eee(c)), to manufacture or sell pharmaceuticals (Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 355(a), (b) and (j); 21 U.S.C. 360(j); 21 C.F.R. 314.1), to acquire another

company (Hart-Scott-Rodino Antitrust Improvements Act of 1976, 15 U.S.C. 18a; 16 C.F.R. 803.1), or to secure a government procurement contract (10 U.S.C. 2313(b); 42 U.S.C. 254(c)) are subject to reporting or records access requirements. The data thus obtained become part of the pool of information available to the recipient federal agency in conducting its business. And, in certain circumstances, such information is available to persons outside the government (e.g., 15 U.S.C. 77f(d); 21 U.S.C. 360(f); 21 U.S.C. 379; 5 U.S.C. 552). This familiar method of regulating commerce is particularly suitable to the manufacture and marketing of potentially hazardous substances such as pesticides.

#### A. The data consideration provisions

From the beginning of its consideration of the appropriate use by EPA of data submitted by pesticide registrants, Congress has been concerned with the statute's impact on the competitive structure of the pesticide industry. Although in 1972 the Senate Committee on Agriculture and Forestry wanted to grant exclusive proprietary rights to data submitters, S. Rep. 92-838, supra, at 6, the Committee on Commerce was concerned that such a provision would raise undesirable barriers to entry in the pesticide market and that it would also compel unnecessarily duplicative expenditures for testing similar products. S. Rep. No. 92-970, supra, at 12.16 The compromise struck by the two committees, which then became law, provided for mandatory licensing, with compensation, of

<sup>16</sup> S. Rep. 92-970, supra, at 12, states:

In effect, whether or not a pesticide has patent protection, a manufacturer wishing to register a pesticide previously registered would have to duplicate the required test data. As patent protection is granted to a substantial number of pesticides, this provision of the bill imposes requirements on subsequent producers beyond the licensing fees that a patent-holder may receive. In the extreme, a monopoly in the production of a pesticide could ensue if competitors are unable to afford the sometimes costly safety and efficacy tests.

testing data previously submitted. By providing for reliance by other companies on the data and the sharing of costs, Congress was plainly acting on its conclusion that data submitters should not have the monopoly benefits of an exclusive use provision. In addition, Congress intended to avoid the "wasteful, time-consuming, and costly process" of requiring subsequent applicants to reinvent the wheel in order to market a previously approved product. S. Rep. 92-838 (Pt. II), supra, at 72-73.

As noted above, see page 11, supra, judicial interpretations of the trade secrets provision of the 1972 Amendments had thwarted Congress's intent to assure a competitive market for pesticides and to promote the efficiency of the registration process. In 1977, the House Committee on Agriculture recognized that the lack of clarity in the 1972 legislation had spawned litigation that had brought the registration process to a standstill. H.R. Rep. 95-663, supra, at 18. In the Committee's view, it was Congress's task to strike (ibid.):

a careful balance between the interests of the small formulator and the need for encouraging competition in the pesticide business, on the one hand, and the need to assure the continued research and development of new pesticides • • •.[17]

The Senate was equally concerned with the impact of the 1972 Amendments on competition. S. Rep. 95-334, 95th Cong., 1st Sess. 3-4 (1977). The Committee on Agriculture, Nutrition and Forestry found there were about 400 manufacturers of basic pesticide chemicals, but that there were only some 40 firms that engage in the development of new pesticide products and that normally generate the health and safety data necessary for registration (id. at 27). In addition, there are thousands of

<sup>&</sup>lt;sup>17</sup> The House bill proposed to achieve that balance by generally providing for a five-year exclusive period followed by a five-year compensation period for test data. H.R. 8681, 95th Cong., 1st Sess. § 2a (1977). See H.R. Rep. 95-663, supra, at 18.

small firms that buy pesticide chemicals for formulation into end-use products but that do little, if any, of the costly testing necessary to obtain a registration. *Id.* at 28. See *id.* at 34 (study prepared by Office of Pesticide Programs, EPA). The Committee noted (*id.* at 30-31) (emphasis added):

The current law in essence treats every firm in exactly the same way and every registration as an autonomous entity. This has resulted in duplication of costs and significant reduction in competition. This was not the intent of the Congress in passing the 1972 amendments. Unfortunately, it is the result.

The amendments also avoid an extension of the patent rights on chemicals. More importantly, these amendments eliminate FIFRA's most severe regulatory impact on the industry—the anti-competitive effects of *de facto* "exclusive use." [18]

It is apparent, then, that Congress reasonably viewed the costs associated with duplicating health and safety data as a significant barrier to entry into the pesticide market, and that its efforts to diminish this barrier effect were rationally related to its objective of fostering competition. See Hodel v. Virginia Surface Mining & Reclamation Ass'n, 452 U.S. at 282; Bowman Transp., Inc. v. Arkansas-Best Freight System, 419 U.S. at 298; United States v. Darby, 312 U.S. 100, 121 (1941).

The district court, ignoring the careful balance Congress struck, instead made its own assessment of the effect of the data consideration provisions and its own

<sup>&</sup>lt;sup>18</sup> To achieve these ends, the Senate Committee recommended no restriction on the consideration of test data by EPA for other applications, but provided a right of compensation for seven years after the submission of the data. S. Rep. 95-334, supra, at 7-8. The conference committee, departing from both the Senate and the House versions, settled on the scheme set out in Section 3(c) (1) (D), 7 U.S.C. 136a(c) (1) (D). S. Conf. Rep. 95-1188, 95th Cong., 2d Sess. 29-31 (1978).

determination of the competitive structure of the industry. Because it concluded that Monsanto's competitors would benefit from the statute, the court found that only private, rather than public, purposes were served by the legislation (J.S. App. 32a). That is not factually or legally accurate. Almost any effort to foster competition is likely to have the effect of benefitting potential competitors, but that fact does not diminish the public nature of the benefits that accrue from increased competition. Moreover, it is well within Congress's powers to employ a regulatory scheme that benefits private persons as a means of achieving its legitimate purposes. Berman v. Parker, 348 U.S. 26, 32-34 (1954). The district court's view that Congress had misjudged the extent of competition in the pesticide industry provided no legitimate basis for overturning the congressional exercise of the commerce power. The legislative history shows that Congress had an adequate basis for concluding that an exclusive use provision (prohibiting EPA from considering prior data in support of subsequent applications) would have undesirable anticompetitive effects. Plainly, the court below erred in displacing Congress's judgment in favor of the court's own view of the matter. Hodel v. Indiana, 452 U.S. at 326. Lastly, the court ignored Congress's express desire to eliminate unnecessary duplicative testing as a means of promoting an efficient and effective registration scheme. See S. Rep. 95-334, supra, at 3-4. 7. This provides an independent basis, apart from the desire to encourage competition, for the data consideration provisions.

## B. The data disclosure provisions

Congress's decision to provide for the disclosure of health and safety data is also a legitimate exercise of the commerce power. Congress repeatedly declared that the potential hazards of pesticide use justified recognition of the public's right to complete information on the safety and efficacy of these items of commerce. S. Rep. 95-334, supra, at 4, 13; H.R. Rep. 95-663, supra, at 18-19, 42.

Disclosure of this information allows members of the public to decide whether and how to use these often inherently dangerous products. The release of this information also informs the public of the basis of EPA's decision to permit the product to be put on the market, and facilitates the public's participation in proceedings under the Act. See National Fertilizer Association v. Bradley, 301 U.S. 178 (1937); Corn Products Refining Co. v. Eddy, 249 U.S. 427, 431 (1919).

The district court concluded, however, that the public need only rely on EPA's decision to register the product and that the public does not require any more information than what is found on the label (J.S. App. 33a). Once again the court impermissibly substituted its judgment for that of Congress. Hodel v. Indiana, 452 U.S. at 326. Moreover, as the district court itself noted (J.S. App. 24a), the label does not provide complete information (J.A. 213-214, 231-232). Neither the label nor the fact EPA has registered the product supplies a basis for understanding or evaluating EPA's conclusion that the product will not cause unreasonable adverse effects on the

<sup>19</sup> As the district court found (J.S. App. 22a), because of the health and safety significance of the data submitted in support of an application for a pesticide registration, EPA often receives requests for access to this information from environmental organizations interested in protecting humans and the environment from the adverse effects of these pesticide chemicals, from farmworker unions that serve to protect the interest of farmworkers who are directly exposed to the pesticides used in the fields where they work, and from union groups that represent the chemical workers who manufacture pesticides (J.A. 249-250, 251-252). Moreover, FIFRA specifically provides for public participation in EPA's decisionmaking process. Members of the public may petition EPA to take regulatory action. See 7 U.S.C. 136a. They may comment in rulemaking proceedings and on other regulatory actions. See, e.g., 7 U.S.C. 136a(b). And they may petition for the commencement of, and participate in, administrative hearings to cancel or deny a pesticide registration. See, e.g., 7 U.S.C. 136d(d); 40 C.F.R. 164.31.

environment.<sup>20</sup> See 7 U.S.C. 136a(c) (5) and (7). Thus, there was ample reason for Congress to rely here on the desirability (recognized by this Court in other contexts) of facilitating public participation in regulatory decisions by making information available to the public. See, e.g., FCC v. Schreiber, 381 U.S. 279 (1965); Utah Fuel Co. v. National Bituminous Coal Comm'n, 306 U.S. 56, 60-62 (1939). Consequently, the district court erred in holding that Congress exceeded its authority by permitting disclosure of safety and health data.

## II. FIFRA'S DATA CONSIDERATION AND DISCLO-SURE PROVISIONS DO NOT TAKE PROPERTY IN VIOLATION OF THE FIFTH AMENDMENT

A. An interest in preserving the exclusive use and secrecy of health and safety data required under FIFRA does not qualify as property protected by the Taking Clause of the Fifth Amendment

The district court's declaration that Sections 3(c) (1) (D) and 10 of FIFRA are unconstitutional rested in part on its determination that Monsanto had an interest in its health and safety data that qualifies as property under the Taking Clause of the Fifth Amendment. Although the court properly rejected Monsanto's claim of a federally-created property right in these data, it accepted the contention that Monsanto has an interest created and protected by state law in maintaining the secrecy and exclusive use of these data and that this interest is property protected by the Fifth Amendment (J.S. App. 29a-30a). The district court found (*ibid.*) a basis for this right in Missouri law, which provides a right to pro-

<sup>&</sup>lt;sup>20</sup> This determination requires the Administrator to assess the "risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide." 7 U.S.C. 136(bb). Of necessity, this determination is a generalized one that will not always apply to every individual instance of the use of a pesticide. A member of the public, therefore, may well have need of the underlying data to evaluate the risk of individual exposure. J.A. 213-14.

tect trade secrets based on the Restatement of Torts § 757 (1939). See Sandlin v. Johnson, 141 F.2d 660 (8th Cir. 1944).

1. Even if the district court were correct in concluding that Monsanto possessed trade secret protection under state law, that finding would not be dispositive of the issues in this case. We start from the common ground that while the data remained exclusively in Monsanto's hands any trade secrets contained in the data would enjoy whatever protections state law afforded. But when Monsanto chose to reveal the data to EPA in exchange for commercially valuable pesticide registrations, it accepted the conditions attendant upon issuance of the registrations. In Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470 (1974), this Court held that state trade secret laws are not preempted as a general matter by the federal patent laws, but the decision acknowledges that Congress possesses the power to supersede such state laws. Id. at 493. Where, as here, Congress has plainly rejected the expansive definition of "trade secrets" contained in the Restatement and has prescribed a uniform procedure for processing registration data, it would contravene the Supremacy Clause for state law to "'stand[] as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." Id. at 479 (quoting Hines v. Davidowitz, 312 U.S. 52, 67 (1941)), See Hancock v. Train, 426 U.S. 167, 179-180 (1976).21

FIFRA comprehensively defines the rights and obligations of EPA with respect to submitted health and safety data. It does so in a manner that necessarily preempts

<sup>&</sup>lt;sup>21</sup> The fact that the Court has held that the federal patent laws have not preempted state trade secret laws, Kewanee Oil Co. v. Bicron Corp., supra, does not control the preemption question under FIFRA. In Kewanee, this Court had to examine the objectives of the patent and trade secret laws for irreconcilable conflict because the patent law does not explicitly address the role of trade secrets. 416 U.S. at 480. In FIFRA, Congress has specifically addressed this question and clearly intended to prescribe uniform rules with respect to the use of pesticide registration data.

conflicting state laws. Indeed, the proper functioning of the registration scheme depends upon uniform application to all data; it cannot, nor did Congress intend it to, vary depending on whether data are submitted from a Missouri company or a firm based in another state. As a result, any continuing right to confidentiality in the data Monsanto submitted to EPA is solely a question of federal law. Chevron Chemical Co. v. Costle, 641 F.2d 104, 116 (3d Cir.), cert. denied, 452 U.S. 961 (1981).

Moreover, the dominance of federal authority in this area is especially strong because the statute defines the duties of a federal agency and its employees. As this Court has held, state law rules cannot regulate the functions of the United States without its consent. EPA v. California, 426 U.S. 200, 211 (1976); Hancock v. Train, supra, 426 U.S. at 178; United States v. Georgia Public Service Commission, 371 U.S. 285, 293 (1963); United States v. County of Allegheny, 322 U.S. 174, 183 (1944).<sup>22</sup>

2. In addition to its error in relying on Missouri law, the district court was also incorrect in finding that FIFRA contravenes the objectives of trade secret protection under state law. The district court relied on the Restatement of Torts definition of "trade secrets," as "any formula, pattern, device or compilation of information which is used in one's business, and which gives him an opportunity to obtain an advantage over competitors who do not know or use it." Id. § 757, comment b. The protection afforded by law to this interest is significantly limited, however, since the basis of liability to the trade secret owner is the breach of a general duty of good faith. Id. at comment a. Thus, one who discloses or uses trade secret information is liable to the owner only if there is

<sup>&</sup>lt;sup>22</sup> Congress's practice of setting the exclusive standard for disclosure of information submitted to federal officials has a lengthy history. The Trade Secrets Act, 18 U.S.C. 1905, prohibits disclosure by federal officials "to any extent not authorized by law." That statute was enacted in 1948 as a codification of earlier laws. See *Chrysler Corp.* v. *Brown*, 441 U.S. 281, 294-298 (1979).

some impropriety associated with the acquisition of the secret (e.g., a breach of a contractual obligation or a breach of confidence arising from a relationship such as that between an employer and employee). Id. § 757. As this Court has recognized, one policy underlying the law of trade secret protection is the need to maintain recognized standards of commercial ethics, Kewanee Oil Co. v. Bicron Corp., 416 U.S. at 481, and therefore protection is provided only when those standards have been breached.23 This unique characteristic of the legal protection provided to trade secrets has led this Court to recognize that the interest of a trade secret owner should not be analyzed as property in the traditional sense. E.I. Du Pont de Nemours Powder Co. v. Masland, 244 U.S. 100. 102 (1917) (Holmes, J.). Indeed, the Restatement of Torts, relied on by Monsanto and the district court, also concludes that the interest of a trade secret owner is not a property interest but merely an interest in ensuring the maintenance of ethical business dealings. Id. § 757, comment a. Thus, any protection is based exclusively on the legal obligations of the particular persons who obtain the secret and therefore have the power to disclose or use it. As we have shown, in this case it is federal law (prescribed in detail by Congress) rather than state law that is the source of these obligations.24

3. The simple fact remains that whatever protections were available to Monsanto prior to its submission of data

<sup>&</sup>lt;sup>23</sup> In this respect, then, trade secret protection differs significantly from the benefits accruing to the holder of a patent; the patentee's right to exclude the use of the invention runs "against the world," and liability for infringement does not depend on a breach of good faith. See Kewanee Oil Co. v. Bicron Corp., 416 U.S. at 489-490; 35 U.S.C. (Supp. V) 154.

 $<sup>^{24}</sup>$  Indeed, the Restatement of Torts explicitly recognizes that a person may have a privilege to disclose or use a trade secret and that such a privilege may be created by law "in order to promote some public interest" (id.  $\S$  757, comment d). Thus, disclosure or use of a trade secret pursuant to a federal law would be privileged conduct under the rule relied on by Monsanto and the district court.

to EPA, it chose to forgo them in order to obtain registrations. Monsanto cannot properly contend that the history and administration of FIFRA created any reasonable expectation to the contrary. Prior to the 1972 Amendments, there were no statutory provisions regarding the consideration of previously submitted data in support of another application for registration. Contrary to the views of the district court, the practice of the Department of Agriculture (and EPA when it took over the administration of the program in 1970) was to grant subsequent "me-too" registrations for pesticides without requiring the duplication of supporting data that had been previously submitted.<sup>25</sup>

The desire to change prior practice and to offset the increasing cost burden of producing registration data was the basis for the industry's request to Congress in 1971 for a right to exclusive use of health and safety data submitted in support of a registration. This proposal was opposed by members of Congress, the Department of Justice, and EPA, who were concerned that an exclusive-use provision would have undesirable anticompetitive effects and force wasteful duplication. S. Rep. 92-970, supra, at 12-13; S. Rep. 92-838 (Pt. II), supra, at 12-13, 69. The compromise reached by Congress provided for compensation to a data submitter when its data were considered by EPA in connection with another application. Thus, contrary to the hopes of Monsanto and some other companies, the 1972 Amendments did not provide for a right of unlimited exclusive use and did not, as a general matter, prohibit EPA from considering previously submitted data.

In enacting these changes, however, Congress excluded from the use and compensation scheme all data that were

<sup>&</sup>lt;sup>25</sup> As shown above, see page 8 & note 8, supra, the record here is so overwhelming on this point that the district court's contrary finding must be deemed clearly erroneous. This Court is not precluded by its Rule 15.1(a) from rejecting this determination, since the legal question whether the 1978 Amendments took property within the meaning of the Fifth Amendment fairly comprises the subsidiary question of the reasonableness of Monsanto's expectations in 1972.

protected from disclosure by Section 10(b) as a trade secret, a term that was not defined by the statute. The 1978 Amendments represent Congress's attempt to rectify the situation created by judicial decisions interpreting the term "trade secret" in the 1972 Amendments in an overly broad manner (see pages 11-13, supra). It is evident from this history that far from possessing a long-standing, investment-backed expectation in preventing the use of health and safety data to approve registrations of other companies, the pesticide industry experienced a period when data requirements were less rigorous and when subsequent registrations were commonly based on another company's data: then, when the cost of producing such data increased significantly, the industry sought from Congress compensating benefits for its efforts. To the extent Congress rejected this request, it is plain that Congress defeated only a "unilateral expectation \* \* \* [and] not a property interest entitled to protection" under the Fifth Amendment. Webb's Fabulous Pharmacies, Inc. v. Beckwith, 449 U.S. 155, 161 (1980). It is on this basis that the Third Circuit has rejected the contention that a data submitter under FIFRA has any property interest protected by the Fifth Amendment. Mobay Chemical Corp. v. Gorsuch, 682 F.2d 419, 423 (3d Cir.), cert. denied, No. 82-241 (Nov. 8, 1982); Chevron Chemical Co. v. Costle, 641 F.2d 104, 116, cert. denied, 452 U.S. 961 (1981).

The principal value of the data to Monsanto is the competitive advantage derived from obtaining a registration. But the ultimate source of that value is not the effort and money expended by Monsanto but the legislative decision to create a licensing scheme, which created the potential for an economic advantage in having a registration. Even though the result of that decision may have been to generate expectations of competitive gain, Congress has the unfettered power to adjust the consequences of its decision (or even to rescind the registration requirement altogether), as this Court has recognized. In Reichelderfer v. Quinn, 287 U.S. 315 (1932), the Court rejected the contention that neighboring landowners had a property right

in the continued dedication of land taken to establish Rock Creek Park in the District of Columbia. As the Court noted (287 U.S. at 319):

Beyond the traditional boundaries of the common law only some imperative justification in policy will lead the courts to recognize in old values new property rights. \* \* \* The case is clear where the question is not private rights alone, but the value was both created and diminished as an incident of the operations of the government. For if the enjoyment of a benefit thus derived from the public acts of government were a source of legal rights to have it perpetuated, the power of government would be exhausted by their exercise.

Since Monsanto's expectations, no matter how strong, were created as an incident to "the public acts of government," there is no warrant to accord them the status of a property interest protected by the Taking Clause.

The same is true with respect to the data disclosure provisions. The data submitted under FIFRA prior to 1972 were generally not disclosed to the public, although the statute itself expressly protected only product formulas, see page 5 & note 5, supra. Notwithstanding any expectation that may have arisen, the 1978 Amendments requiring disclosure do not defeat an interest of indedependent significance. As the district court found, the data are generated primarily for registration purposes (J.S. App. 21a); the competitive edge lies in the contribution the data make to obtaining a registration. But the statute specifically provides for the circumstances under which a particular company's data may or may not be considered, and these provisions operate independently of any authority to disclose the information. We have shown that Monsanto may not depend on its unilateral expectations to upset these rules, and in these circumstances, disclosure or nondisclosure no longer functions to control the primary business use of the data. There remains, then, no basis for concluding that the continued secrecy of this information is a substantial property interest protected by the Fifth Amendment.

B. Even if Monsanto does possess a protected property right in its test data, the 1978 Amendments are not a taking of that interest

Even if this Court were to conclude that Monsanto's expectations in controlling the use and disclosure of its data amounted to a protected property interest, the operation of the 1978 Amendments do not "take" this property within the meaning of the Fifth Amendment. Although this Court has on many occasions considered whether a governmental action constituted a taking, no simple formula for adjudging such claims has been established. Penn Central Transp. Co. v. New York City, 438 U.S. 104, 123-124 (1978). The essence of the inquiry is a weighing of the private interests against the public interest to determine if "justice and fairness" require the government to compensate for the economic injuries caused by governmental action. Agins v. City of Tiburon, 447 U.S. 255, 260-261, 262-263 (1980); Andrus v. Allard, 444 U.S. 51, 66 (1979); Penn Central, 438 U.S. at 124.

Among the factors to be considered in any particular case the economic effect on the claimant, specifically the extent to which the government's action interferes with "distinct investment-backed expectations." Penn Central. 438 U.S. at 124. An important consideration is whether the regulation destroys all property rights or renders the claimant unable to derive any economic benefit from the property. Andrus v. Allard, 444 U.S. at 65-67. "[W] here an owner possesses a full 'bundle' of property rights, the destruction of one 'strand' of the bundle is not a taking, because the aggregate must be viewed in its entirety." Id. at 65-66.

Equally important, however, is the nature of the government action, since interference caused by a "public program adjusting the benefits and burdens of economic life to promote the common good," in contrast to a physical invasion or appropriation of property, more readily passes constitutional muster. 444 U.S. at 65-66. The Court, after weighing the public interest and the public purposes served by the alleged taking, has sustained government actions that have had the effect of destroying or severely affecting property interests. Goldblatt v. Hempstead, 369 U.S. 590 (1962) (ordinance that effectively prohibited continuation of pre-existing business of sand and gravel mining); United States v. Central Eureka Mining Co., 357 U.S. 155, 166-168 (1958) (government order prohibiting operation of private gold mines for two years); Miller v. Schoene, 276 U.S. 272, 279 (1928) (government order to destroy cedar trees that threatened to inflict disease on nearby commercial apple orchards). When tested against the standards developed and applied by this Court. Monsanto's claim of a taking must be rejected, as it has been by every court other than the court below that has considered the question. See Mobay Chemical Corp. v. Costle; supra,; Pennwalt Corp. v. Gorsuch, No. 80-2400 (W.D. Pa. July 23, 1982), aff'd as a companion case in Mobay, supra; Chevron Chemical Co. v. Costle, 499 F. Supp. 732 (D. Del. 1980), aff'd on other grounds, 641 F.2d 104 (3d Cir.), cert, denied, 452 U.S. 961 (1981); Petrolite Corp. v. EPA, 519 F. Supp. 966 (D. D.C. 1981). See also Union Carbide Agricultural Products Co. v. Costle, 632 F.2d 1014 (2d Cir. 1980), cert. denied, 450 U.S. 996 (1981).

## 1. The data consideration provisions

Section 3(c) (1) (D) defeats Monsanto's claimed expectation that it would retain control of the exclusive use of its health and safety data. As we have shown (pages 31-32, supra), these expectations do not provide a foundation for a taking claim. Moreover, the district court found that despite the enactment of the 1978 Amendments, Monsanto continues to expand its research and development and to submit data to EPA (J.S. App. 21a; J.A. 106, 213). Thus, even if these expectations technically qualify as a property interest, they are so insubstantial that even their total destruction should count for little

when reckoned against the public interest served by the legislation.

In addition, there is, of course, no physical invasion as might be the case with real property, but there is also no appropriation of Monsanto's property by the government. The government does not market pesticides; it uses the data in furtherance of the congressionally-created regulatory scheme. While other companies may obtain a registration on the basis of Monsanto's data, Section 3(c)(1)(D) does not afford those companies any other rights in this information. Nor are they entitled to examine the data under this subsection.

The district court reasoned (J.S. App. 31a-32a) that Section 3(c)(1)(D) completely destroys Monsanto's "fundamental right \* \* \* to exclude" others from its property and, therefore, that a taking had been established. But this Court has unequivocally held that interference with the right to exclude does not by itself constitute a taking. Pruneyard Shopping Center v. Robins, 447 U.S. 74, 84 (1980). The "right to exclude" is merely one "strand" in Monsanto's "bundle" of rights. As the district court recognized, Monsanto retains significant rights in its data (J.S. App. 18a, 21a, 23a). First, Monsanto used its data to obtain valuable registrations for its products and Section 3(c) (1) (D) does not interfere with its continuing right to market those products. Second, Monsanto retains the right to exploit the data to develop new products or new uses for old products and to obtain domestic or foreign registrations for them (J.S. App. 18a, 21a; J.A. 212). Third, Monsanto retains the right to use the data outside the registration process for purposes such as advertising and marketing its products, defending claims against its products, and enhancing its reputation in the agricultural and scientific communities (J.S. App. 21a, 23a; J.A. 77, 209-212; Tr. 268-269). Since Monsanto has not lost these significant rights in its data, the limited interference Congress has mandated does not constitute a taking. Pruneyard Shopping Center v. Robins, 447 U.S. at 84; Andrus v. Allard, 444 U.S. at 65-66.26

Other factors also show that the economic impact on Monsanto is not so substantial as to warrant a conclusion that the statute takes its property. The value of Monsanto's "right to exclude" is in reality only an element of the competitive position Monsanto enjoys in the marketplace. It is therefore appropriate to assess the impact of the statute on the entire range of competitive advantages Monsanto enjoys. On this score, the interference is not nearly so devastating as Monsanto asserts. The district court concluded that the company retains its primary sources of competitive advantage, including its product and use patents, its advertising and marketing techniques, and lead-time advantages not related to the exclusive use or secrecy of data (J.S. App. 18a-21a, 23a; J.A. 93, 102, 106-108, 136-137, 159-160, 164-165, 188-189, 204-206, 209-210).

Moreover, companies like Monsanto won from Congress a measure of protection for their data and the competitive advantage that the information may provide. Monsanto retains a 10-year exclusive use period for data submitted on any new active ingredient registered after 1978 and is entitled to compensation for use of other data submitted after 1969 for a 15-year period. These valuable replacement rights mitigate the burden of government action and militate strongly against a conclusion of a taking. Penn Central, 438 U.S. at 137. An additional benefit that Monsanto gains under the the statute is the reciprocal right to rely on its competitors' data to obtain registrations and to enter the market with a particular pesticide product. The statute thus "secures an average reciprocity of advantage" and may be sustained on this basis as well. Pennsylvania Coal Co. v. Mahon, 260 U.S. 393, 415 (1922).

<sup>&</sup>lt;sup>26</sup> See Gannon, FIFRA and the "Taking" of Trade Secrets, 8 B. C. Envtl. Aff. L. Rev. 593, 632-636 (1980).

It is clear from this survey that the principal competitive impact of the data consideration provisions is to reduce barriers to entry by allowing subsequent applicants to obtain registrations for products not covered by patents without duplicating test data EPA already has in its possession. This procompetitive impulse is, of course, precisely what Congress intended and is fully consonant with the purpose of the patent laws to foster competitive imitation once the 17-year period of exclusivity has expired. It is not unexpected that such an increase in competition will affect the market position of an innovator who had enjoyed a statutory monopoly, and may lead to reduced profits. But, "loss of future profits-unaccompained by any physical property restriction-provides a slender reed upon which to rest a takings claim," Andrus v. Allard, 444 U.S. at 66.

### 2. The data disclosure provisions

Similarly, the limited interference, if any, with Monsanto's use of its data that is attributable to the data disclosure provisions does not constitute a taking. What is at issue here is only the disclosure of health and safety data to certain classes of persons. Section 10 prevents, except in limited circumstances, the disclosure of a company's confidential product formulas and information about manufacturing and quality control processes. 7 U.S.C. 136h(d)(1)(A), (B), and (C). Moreover. Section 10(g) prohibits the knowing disclosure of any information to foreign or multinational businesses engaged in pesticide production or marketing. 7 U.S.C. 136h(g).27 Nor does the fact of disclosure by itself place Monsanto at a competitive disadvantage in relation to other applicants for registration since the data consideration provisions permit EPA to rely on Monsanto's data to issue other registrations without the applicant having seen the data.

<sup>&</sup>lt;sup>27</sup> The district court found that most, if not all, of the large firms that do research and testing on pesticides are engaged in foreign or multinational pesticide marketing (J.S. App. 4a; J.A. 208).

Moreover, Monsanto retains other significant rights to exploit the data that do not depend on the continued confidentiality of the information. As the district court concluded (J.S. App. 21a), Monsanto developed the data primarily to obtain pesticide registrations, which are commercially valuable marketing licenses. Disclosure of data does not affect the continuation of Monsanto's registrations; nor does it prevent the company from using previously submitted data to obtain registration for new products or new uses for approved products. Indeed, as noted, see page 34, supra, Monsanto's research and development efforts have accelerated, rather than diminished, since the passage of the 1978 Amendments.

Monsanto simply has not made out a case of substantial and particularized interference with its interest in maintaining the secrecy of health and safety data that were submitted to the federal government. The public interest served by this provision, on the other hand, is quite substantial. Congress found here an overriding public policy to promote knowledge about the safety and efficacy of pesticide products, many of which are inherently dangerous. See page 34, supra. In addition to permitting members of the public to evaluate and adjust their own exposure to pesticides, the disclosure provisions also allow the public to stand on the same footing as the agency and the industry in proceedings under the statute. This Court has recognized the propriety and, indeed, the desirability of obtaining public input by making information on regulatory decisions available to the public. See, e.g., FCC v. Schreiber, 381 U.S. 279 (1965); Utah Fuel Co. v. National Bituminous Coal Comm'n, 306 U.S. 56, 60-62 (1939).

The district court's contrary conclusion was based on its determination that the product label and the registration provide all the protection and information the public needs. The courts, however, are not at liberty to dismiss so cavalierly the contrary conclusions of Congress. *Hodel* v. *Indiana*, 452 U.S. at 326. Moreover, the district court

was wrong. Neither the fact of registration nor the label provides all the information necessary for persons who use or are exposed to pesticides to evaluate fully their safety in particular applications. Cf. Federal Security Administrator v. Quaker Oats Co., 318 U.S. 218, 229-231 (1943).

Furthermore, this Court's decisions have long-since established the basic proposition that there is a legitimate public interest in requiring disclosure of trade secrets or proprietary information for the benefit of consumers that will defeat a taking claim. The Court has sustained a state statute, designed to foster agriculture within the state, that required the disclosure of the proportions of ingredients in a fertilizer mixture, National Fertilizer Association v. Bradley, 301 U.S. 178, 182 (1937), and has approved a similar requirement to disclose the ingredients of table syrup. Corn Products Refining Co. v. Eddy, 249 U.S. 427, 431 (1919). In-rejecting claims that these statutory disclosure provisions unlawfully deprived companies of property, the Court declared in language fully applicable here that (249 U.S. at 431-432):

it is too plain for argument that a manufacturer or vendor has no constitutional right to sell goods without giving to the purchaser fair information of what it is that is being sold. The right of a manufacturer to maintain secrecy as to his compounds and processes must be held subject to the right of the State, in the exercise of its police power and in the promotion of fair dealings, to require that the nature of the product be fairly set forth. [28]

Monsanto has not demonstrated that the balance Congress struck between the interest in secrecy and the public's right to be informed of the risks inherent in pesticides was so destructive of its expectations that it may escape the rule of Corn Products and National Fertilizers Asso-

<sup>28</sup> See 301 U.S. at 182.

ciation.<sup>29</sup> Although Congress has made a limited adjustment in Monsanto's rights regarding the data, the company must bear that burden in exchange for "the advantage of living and doing business in a civilized community.'" Andrus v. Allard, 444 U.S. at 67 (quoting Pennsylvania Coal Co. v. Mahon, 260 U.S. 393, 422 (1922) (Brandeis, J., dissenting)).

# III. EVEN IF FIFRA'S DATA CONSIDERATION AND DISCLOSURE PROVISIONS TAKE MONSANTO'S PROPERTY, THE DISTRICT COURT ERRED IN GRANTING INJUNCTIVE RELIEF

As we have shown, Sections 3(a)(1)(D) and 10 do not cause a "taking" of Monsanto's property. But even if the district court's contrary conclusion were correct, Monsanto would not be entitled to injunctive relief. A taking

<sup>&</sup>lt;sup>29</sup> A similar balance has been struck in a great number of federal statutes that authorize or require public disclosure of information submitted by private firms to the government. We have already referred (pages 20-21, supra) to federal statutes that require firms seeking to engage in regulated activity to disclose data they might otherwise choose not to reveal. In addition, many federal statutes provide for disclosure of allegedly "trade secret" information concerning potential hazards to public health. For example, notwithstanding trade secrecy claims, the Toxic Substances Control Act requires public disclosure of "health and safety data" concerning chemical substances and mixtures distributed in commerce (except for manufacturing processes and some formula information), 15 U.S.C. 2613(b); the Clean Air Act requires disclosure of "emission data," 42 U.S.C. (Supp. V) 7607(a)(1); the Federal Water Pollution Control Act requires disclosure of "effluent data," 33 U.S.C. 1318(b); and the Safe Drinking Water Act requires disclosure of all data concerning drinking water contaminants, 42 U.S.C. 300j-4(d). See also 42 U.S.C. 263g(d), requiring disclosure of trade secret data concerning radiation emissions from electronic products such as microwave ovens; 42 U.S.C. 5413(c)(5). requiring disclosure of trade secret data concerning safety-related defects in mobile homes: 46 U.S.C. 1464(d), authorizing disclosure of trade secret information regarding safety defects in boats and boating equipment; and 15 U.S.C. 2217, authorizing trade secret fire protection information to be disclosed when "necessary in order to protect health and safety."

of private property may not be enjoined as unconstitutional if the taking has been duly authorized, if it serves a public purpose, and if the owner will be able to receive just compensation for the property taken. See, e.g., Duke Power Co. v. Carolina Environmental Study Group, Inc., 438 U.S. 59, 94 n.39 (1978); Regional Rail Reorganization Act Cases, 419 U.S. 102, 126-127 and n.16 (1974); Larson v. Domestic & Foreign Commerce Corp., 337 U.S. 682, 697 n.18 (1949). In this case, all three of these conditions are satisfied.

It is not disputed that EPA's consideration and disclosure of Monsanto's data are duly authorized by Sections 3(c)(1)(D) and 10. Moreover, as we have shown, pages 20-27, supra, both sections serve important public purposes. Thus, the only remaining issue is whether just compensation will be provided. As we will discuss, the statute provides some measure of compensation under the data consideration provisions. In addition, the Tucker Act, 28 U.S.C. 1491, provides Monsanto the means to obtain whatever additional just compensation is due for any "taking." See Chevron Chemical Co. v. Costle, 499 F. Supp. at 742-743. See also Union Carbide Agricultural Products Co. v. Costle, 632 F.2d at 1019; Dow Chemical Corp. v. Costle, 464 F. Supp. 395, 399 (E.D. Mich. 1978).

The district court erred in holding that Congress withdrew the Tucker Act remedy when it enacted FIFRA. The dispositive inquiry is "not whether the [challenged statute] expresses an affirmative showing of congressional intent to permit recourse to a Tucker Act remedy \* \* \*," but rather whether Congress has "withdrawn the Tucker Act grant of jurisdiction to the Court of Claims to hear a suit involving the [challenged statute] "founded . . . upon the Constitution." Regional Rail Reorganization Act Cases, 419 U.S. at 126 (emphasis in original). This rule of construction is based on the general principle that "whether or not the United States so intended," a taking claim is one "founded upon the Constitution" within the meaning of the Tucker Act and therefore within the Claims Court's jurisdiction. 419 U.S. at 126 (emphasis

supplied); United States v. Causby, 328 U.S. 256, 267 (1946). As this Court stated in Yearsley v. W.A. Ross Construction Co., 309 U.S. 18, 21 (1940):

[I]f the authorized action \* \* \* does constitute a taking of property for which there must be just compensation under the Fifth Amendment, the Government has impliedly promised to pay that compensation and has afforded a remedy for its recovery by suit in the Court of Claims.

In this case, there is no indication in the statute or its history that Congress intended to impair the jurisdiction of the Claims Court by withdrawing the Tucker Act remedy. No language in FIFRA amends the Tucker Act, or otherwise purports to deny the liability of the United States. There is no discussion in the legislative history indicating that Congress thought any taking under the Fifth Amendment would occur, much less that the United States should curtail the waiver of its sovereign immunity against compensation claims.<sup>30</sup>

The district court mistakenly relied on the statute's creation of a procedure for original data submitters to obtain compensation from subsequent applicants. It is certainly not a necessary inference from this statutory mechanism for spreading among private parties the cost of testing pesticides that Congress also intended to extinguish any claims against the United States. To be sure,

<sup>&</sup>lt;sup>30</sup> Monsanto has relied on a floor statement of Senator Leahy containing the phrase "just compensation." 123 Cong. Rec. 25709 (1977) (Mot. to Aff. 26). The statement contains no reference to the Fifth Amendment or the Tucker Act and appears to represent nothing more than the Senator's view that compensation awarded under the arbitration scheme should be fair and reasonable. Moreover, this issue had been raised in litigation under the 1972 and 1975 Amendments. In 1976, well before the consideration and passage of the 1978 Amendments, one district court had denied a preliminary injunction on a taking claim because of its determination that the Tucker Act remedy had not been withdrawn. *Dow Chemical Corp.* v. *Train*, 423 F. Supp. 1359, 1364 (E.D. Mich. 1976).

Congress provided for what it thought was an appropriate reward for the use of a company's health and safety data. But that fact does not support a conclusion that Congress also blocked a company's recourse for losses for which the Constitution requires compensation and which were not fully offset by the amounts awarded under the statutory compensation scheme. Regional Rail Reorganization Act Cases, supra; Pennsylvania v. ICC, 535 F.2d 91, 97-98 (D.C. Cir. 1976).

This Court considered a similar situation in the Regional Rail Reorganization Act Cases, supra. There Congress had sought to solve a major rail transportation crisis by reorganizing several major railroads into a single system operated by a private, state-incorporated entity. 419 U.S. at 108-111. As part of this plan, certain rail properties were to be transferred to the new corpora-Congress explicitly recognized that the Fifth Amendment would require just compensation for this transfer and provided for compensation in the form of securities of the new corporation, certain governmentbacked obligations and other benefits. 419 U.S. at 111. In disposing of a claim that the resulting compensation would not meet the constitutional minimum, this Court concluded that Congress's express consideration of and provision for compensation due under the Fifth Amendment did not support an inference that it had withdrawn the remedy under the Tucker Act to make up any constitutional shortfall in the statutory compensation. 419 U.S. at 128-131. In the instant case, the support for such an inference is even weaker because Congress did not expressly consider any question of compensation due under the Fifth Amendment.31 Thus, even if the data disclosure

<sup>&</sup>lt;sup>31</sup> The district court's other reasons for finding a congressional intent to foreclose relief under the Tucker Act are also without merit. It is of no significance that no monies were allocated for compensation (see J.S. App. 36a). Such an appropriation is not customary and is not a prerequisite to jurisdiction of the Claims Court under the Tucker Act. See Yearsley v. W.A. Ross Constr.

and consideration provisions do work a "taking" of Monsanto's property, it was erroneous for the district court to enjoin their implementation as unconstitutional—at least in the absence of willingness by the United States as a litigant to have the statutory scheme enjoined rather than to provide by means of the Tucker Act remedy whatever compensation is constitutionally required. Regional Rail Reorganization Act Cases, 419 U.S. at 102; Chevron Chemical Co. v. Costle, 499 F. Supp. at 742-743.

- IV. THE CONSTITUTIONAL CHALLENGES TO THE ARBITRATION AND COMPENSATION SCHEME ARE NOT RIPE FOR RESOLUTION AND IN ANY EVENT ARE WITHOUT MERIT
  - A. The district court erred in considering Morganto's constitutional attacks on the arbitration and compensation scheme in Section 3(c)(1)(D)(ii)

In addition to holding that the statute unconstitutionally takes Monsanto's property, the district court invalidated the arbitration and compensation scheme provided for in Section 3(c)(1)(D)(ii). Since Congress determined that health and safety testing data need be submitted only once for a particular pesticide, that provision was intended to allocate the costs of performing the tests among all companies who seek to have EPA consider the data in passing on registration applications. If a com-

Co., 309 U.S. at 21 (in the case of a taking, the government impliedly promises to pay); Hurley v. Kincaid, 285 U.S. 95, 104 (1932) (compensation need not precede the taking). Finally, the district court's view (J.S. App. 36a) that the Tucker Act is not an adequate remedy because FIFRA works an "immediate taking of Monsanto's property as of the passage of the amendments to FIFRA" is unfounded. Obviously, if any taking occurs, it occurs only when EPA actually considers Monsanto's data to support another application or discloses the data. FIFRA itself does not automatically confiscate Monsanto's data. FIFRA merely provides for EPA's consideration and disclosure of the data under specified circumstances.

pany submits data for which the statute requires compensation, the firm that is seeking to have EPA consider the data must make an offer of compensation to the original submitter, 7 U.S.C. 136a(c)(1)(D)(ii). If the parties cannot agree on the amount of compensation, either party may initiate binding arbitration through the Federal Mediation and Conciliation Service. Ibid. The decision of the arbitrator is final and unreviewable except in the case of "fraud, misrepresentation, or other misconduct" by the parties or the arbitrator. Ibid. The district court concluded (J.S. App. 34a-36a) that this provision was invalid because: (1) it did not provide the constitutionally required just compensation; (2) it offended the Due Process Clause; and (3) it delegated judicial power to a non-Article III forum. The attack on this provision, however, was premature since Monsanto did not allege or establish that it had been injured by an actual arbitration under the statute. In these circumstances, the issues were not ripe for review.

Ripeness is a threshold element of Article III's requirement of a case or controversy. See Duke Power Co. v. Carolina Environmental Study Group, Inc., 438 U.S. at 81; Regional Rail Reorganization Act Cases, 419 U.S. at 138. Accordingly, federal courts are without jurisdiction to adjudicate hypothetical disagreements or abstract claims before action has been taken that has a concrete effect on an aggrieved party. Abbott Laboratories v. Gardner, 387 U.S. 136, 148-149 (1967); Toilet Goods Association v. Gardner, 387 U.S. 158, 164 (1967). To determine if a question is ripe for review, the Court must consider the "fitness of the issues for judicial decision" and weigh that consideration against "the hardship to the parties of withholding court consideration." Abbott Laboratories v. Gardner, 387 U.S. at 149.

In this case, the asserted claims of unconstitutionality are premature in the absence of a specific arbitration award. The statute itself inflicts no harm on Monsanto. The company claims that the alleged defects in the statute will prevent it from receiving the compensation that is due under the statute and the Constitution, but that conclusion depends entirely on the amount Monsanto may receive in any given case.<sup>32</sup> The matter is wholly speculative at present.<sup>33</sup> If the amount awarded to Monsanto in any future arbitration is satisfactory, there would be no occasion to decide whether the process comported with the Fifth Amendment or whether an Article III judge was required to make or review the award.

Precisely the same considerations led this Court to dismiss as premature a similar attack on a statutory requirement for binding arbitration. Babbitt v. United Farm Workers Nat'l Union, 442 U.S. 289, 304-305 (1979). In that case, an Arizona statute required binding arbitration of a labor dispute between farm workers and agricultural employers if there was a strike and if the employer responded by obtaining a temporary restraining order enjoining the strike. The Court held that so long as there was a possibility of settling such disputes through negotiation and without the need to invoke the challenged

<sup>&</sup>lt;sup>32</sup> Monsanto's claim that the arbitration procedure will not provide the just compensation required by the Fifth Amendment is precluded by the availability of the Tucker Act remedy. See pages 41-44, supra.

<sup>33</sup> Monsanto would suffer concrete injury only after a series of discrete, independent events. First, a company must apply for a registration and seek to rely on data submitted by Monsanto and compensable under Section 3(c) (1) (D). Second, that company must make a compensation offer to Monsanto. Third, EPA must decide to grant the registration. Fourth, Monsanto and the other company must fail to reach agreement on the amount of compensation. Fifth, arbitration must be initiated and the arbitrator must make an award. At any stage of such proceedings, Monsanto's statutory right to compensation may not mature or may be fully satisfied. It is apparent that no immediate injury is caused by the enactment of the statute and that such injury is not the inexorable result of the legislation. The existence of the many possible contingencies shows that the claimed injury is speculative and the issues presented hypothetical. See Toilet Goods Association, v. Gardner, 387 U.S. at 163-164.

arbitration procedures, "any ruling on the compulsory arbitration provision would be wholly advisory." 442 U.S. at 305.

In addition, there is no hardship to Monsanto in withholding judicial review at this time. If and when Monsanto receives an award that in its view is inadequate and illegal, the company may bring an action to challenge the award and present its constitutional claims in that proceeding. The expense and inconvenience of pursuing the arbitration procedures and bringing an action in the district court is not the kind of hardship that would avoid a finding that the claim is currently premature. See FTC v. Standard Oil Co., 449 U.S. 232, 234 (1980).

## B. Neither the Due Process Clause nor Article III requires invalidation of the arbitration and compensation scheme

Even if Monsanto's claims were ripe for review, the district court erred on the merits. First, binding arbitration of statutorily created entitlements does not offend due process. Hardware Dealers Mutual Fire Insurance Co. v. Glidden Co., 284 U.S. 151, 157-158 (1931) (state statute mandating arbitration of the amount of loss under insurance policy). See also Andrews v. Louisville & N. RR., 406 U.S. 320, 322 (1972) (compulsory arbitration provision of the Railway Labor Act for minor disputes, 45 U.S.C. 153 First (i)). Nor do the statute's limitations on judicial review call for a different result. In Crane v. Hahlo, 258 U.S. 142 (1922), this Court upheld a statute that declared that compensation awards for

<sup>&</sup>lt;sup>34</sup> One such proceeding, not involving Monsanto, is currently pending in the United States District Court for the District of Columbia. *PPG Industries, Inc.* v. Stauffer Chemical Co., C.A. No. 83-1941 (filed July 7, 1983). Plaintiff in that action has attacked Section 3(c)(1)(D) as unconstitutional under the Due Process Clause, the Taking Clause and Article III.

damage caused by municipal construction work were final and unreviewable. The Court concluded that as long as the process was efficient and the courts could remedy jurisdictional defects, fraud or willful misconduct of the board making the awards, the statute satisfied the Due Process Clause. 258 U.S. at 147-148. See Edwards v. St. Louis-S.F. R.R., 361 F.2d 946, 955 (7th Cir. 1966). See also Switchmen's Union v. National Mediation Board, 320 U.S. 297, 300-301 (1943); Ludwig Honold Mfg. Co. v. Fletcher, 405 F.2d 1123, 1127-1128 (3d Cir. 1969).

There is no basis for the district court's further conclusion that the statute is unconstitutionally vague for failing to provide standards for determining the measure of compensation. The 1972 Amendments provided for the right to "reasonable compensation for providing the test data to be relied upon." § 3(c) (1) (D), 86 Stat. 980. The stated purpose was to spread the costs of data development (S. Rep. 92-838 (Pt. II), supra, at 69). The intended measure of compensation was plainly the equitable division of those costs. In 1978, Congress substantially altered the procedural aspects of the arbitration and compensation scheme, assigning the determination of the amount of compensation to the parties and the arbitrator rather than to EPA. See pages 12-13, supra. It is clear from the legislative history, however, that no change in the expected measure of compensation was intended. See S. Rep. 95-334, supra, at 7-8. Senator Leahy explained in floor debate that the scheme "protects the data developer's right to recover his data generation costs \* \* \*." 123 Cong. Rec. 25706 (1977) (emphasis added). Contrary to the district court's conclusion, a constitutionally satisfactory measure for compensation under Section 3(c) (1) (D), the equitable division of data development costs, can be derived from the statute and its history.

Finally, it does not violate Article III of the Constitution to assign the resolution of a compensation dispute to an arbitrator whose decision is subject to limited judicial review.<sup>35</sup> This Court has frequently upheld laws delegating the determination of statutorily-created rights to administrative bodies without any judicial review. See South Carolina v. Katzenbach, 383 U.S. 301, 333 (1966); Switchmen's Union v. National Mediation Board, 320 U.S. at 300-301, 303. See also Andrews v. Louisville & N. R.R., supra; Crane v. Hahlo, supra.<sup>36</sup>

[W]hen Congress creates a statutory right, it clearly has the discretion, in defining that right, to create presumptions, or assign burdens of proof, or prescribe remedies; it may also provide that persons seeking to vindicate that right must do so before particularized tribunals created to perform the specialized adjudicative tasks related to that right.

Thus, both the court below and the district court in *Union Carbide Agricultural Products Co.* v. *Ruckelshaus*, 571 F. Supp. 117 (S.D. N.Y. 1983), erred in relying on *Northern Pipeline* to strike down the arbitration provision.

<sup>36</sup> Moreover, even if this Court were to resolve the Article III issue in Monsanto's favor, that would not justify enjoining the entirety of Section 3(c) (1) (D), but only the limitation on judicial review contained in the fourth sentence of Section 3(c) (1) (D) (ii). See 2 C. Sands, Statutes and Statutory Construction § 44.04 (4th ed. 1973); 7 U.S.C. 136x (severability). In this respect, the judgment entered on November 29, 1983 in Union Carbide Agricultural Products Co. v. Ruckelshaus, supra, was too broad since it barred EPA from considering any data that would be subject to the arbitration provisions in Section 3(c) (1) (D) (ii).

<sup>35</sup> This Court's recent decision in Northern Pipeline Construction Co. v. Marathon Pipe Line Co., 458 U.S. 50 (1982), is not to the contrary. The vice of the 1978 Bankruptcy Act was the assignment to the bankruptcy courts of the authority to adjudicate traditional common law rights (id. at 81-86); the challenged provisions of FIFRA deal only with a statutorily-created right of recent vintage. Indeed, the plurality in Northern Pipeline reaffirmed Congress's constitutional authority to proceed in this manner (id. at 83 (footnote omitted)):

#### CONCLUSION

The judgment of the district court should be reversed and the case remanded with instructions to vacate the injunction and to dismiss the complaint.

Respectfully submitted.

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DECEMBER 1983

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IN THE

# Supreme Court of the United States

OCTOBER TERM, 1983

WILLIAM D. RUCKELSHAUS, ADMINISTRATOR, UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, Appellant

V.

MONSANTO COMPANY

On Appeal From The United States District Court For The Eastern District Of Missouri

## BRIEF OF APPELLEE MONSANTO COMPANY

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### THE QUESTION PRESENTED

Whether the disclosure and private use provisions of the 1978 amendments to the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. §§ 136a(c)(1)(D), the last sentence of 136a(c)(2)(A), 136h(b), and 136h(d)(1982)) take private property in the form of trade secrets in violation of the Fifth Amendment to the Constitution.

# TABLE OF CONTENTS

	Page
STATEMENT	1
A. The FIFRA Amendments At Issue	3
B. The Effect Of The District Court's Injunction	8
SUMMARY OF ARGUMENT	10
Argument	13
I. Monsanto's Trade Secrets Are "Private Proper- ty" Within The Meaning Of The Taking Clause	13
A. Introduction	13
B. The Term "Property" In The Taking Clause Includes Trade Secrets	14
C. Monsanto's Trade Secrets Are The Result Of An Enormous Commitment Of Time, Money And Effort	21
D. EPA's Arguments That Monsanto's Trade Secrets Should Not Be Considered "Property" Conflict With The Taking Clause	25
II. THE 1978 FIFRA AMENDMENTS TAKE MONSANTO'S TRADE SECRET PROPERTY	31
III. "JUST COMPENSATION" IS NOT PROVIDED FOR THE TAKING OF MONSANTO'S TRADE SECRET PROPERTY.	40
IV. THE 1978 FIFRA AMENDMENTS TAKE MONSANTO'S TRADE SECRETS FOR A PRIVATE USE IN VIOLATION OF THE FIFTH AMENDMENT	45
Conclusion	49

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Pa	age
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	Page
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## IN THE

# Supreme Court of the United States

OCTOBER TERM, 1983

No. 83-196

WILLIAM D. RUCKELSHAUS, ADMINISTRATOR, UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, Appellant

V.

### MONSANTO COMPANY

On Appeal From The United States District Court For The Eastern District Of Missouri

# BRIEF OF APPELLEE MONSANTO COMPANY

#### STATEMENT

Trade secrets are an important form of property in the United States. Promoting innovation and scientific advancement, the protection of trade secrets is vital to the existence of many high-technology sectors of the economy. One such sector is the pesticide industry, which confers enormous benefits on American agriculture.

Successful pest controls have been largely responsible for dramatic improvements in yields on the nation's farms during the last 40 years. Despite great technological advances since

<sup>&</sup>lt;sup>1</sup>S. Rep. No. 334, 95th Cong., 1st Sess. 32 (1977). For example, the elimination of pesticides to control weeds "and the use of economically feasible nonchemical means (rotation, sanitation, biocontrol, etc.) would reduce annual farm revenues 31% resulting in economic losses (based on 1976 figures) of \$13.0 billion," which would cause "severe shortages of food and [Footnote continued]

World War II, pests continue to destroy one-third of the world's food crop; many pests remain uncontrolled and others have become resistant to existing control methods. As a result, "pest control research necessarily entails a ceaseless search for new practices just to 'stay even.' This includes the search, now primarily in the private sector, for more effective and safer pesticides."

In its quest for better pesticides, Monsanto Company develops valuable property in the form of trade secrets. These trade secrets are contained in Monsanto's research and test data, which the company submits to the Environmental

fiber in the U.S. and result in a 50% or greater increase in food prices to the American public." Abernathy, Estimated Crop Losses Due to Weeds with Nonchemical Management, in 1 CRC Handbook of Pest Management in Agriculture 159 (1981).

<sup>2</sup> National Research Council Report to the President, World Food and Nutrition Study 81 (1977). See, e.g., Journal of International Agriculture, World Crops 156 (Sept./Oct. 1982); G. Ware, Pesticides: Theory and Application 5 (1983). The world's main source of food—plants—compete with 30,000 species of weeds, are susceptible to 100,000 diseases and are attacked by 10,000 species of plant-eating insects. Id.

<sup>3</sup> The term "pesticides" includes herbicides, insecticides, rodenticides and plant regulators. See 7 U.S.C. § 136(u)(1982).

<sup>4</sup> The Statement of Parties to the Proceedings, pursuant to Supreme Court Rule 28.1, appears at page ii of Monsanto's Motion to Affirm. In the interim, Monsanto has acquired a 50% interest in Control Specialist (Pty.), Ltd. and Nippon Fisher Company, Ltd.

The following abbreviations are used in this brief: "J.A." (Joint Appendix in this Court); "J.S." (EPA's Jurisdictional Statement); "J.S. App." (Appendix to EPA's Jurisdictional Statement reprinting the district court's decision, now reported at 564 F. Supp. 552); "Mot. Aff." (Monsanto's Motion to Affirm); "EPA Brief" (brief on merits for the appellant); "Tr." (trial transcript).

<sup>5</sup> Monsanto conducts extensive research aimed at discovering new chemicals that have the potential to be transformed into commercially successful pesticides. J.A. 131-33. See pages 21-25 infra. Although Monsanto has laboratories in Europe, South America and Asia, its pesticide research is primarily conducted at Monsanto's facilities in St. Louis, Missouri. J.A. 116-17; J.S. App. 2a.

Protection Agency (EPA) to support Monsanto's registration of pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).

The issues in this case focus on whether the government may deprive Monsanto of this property by publicly disclosing the company's research and test data and by allowing Monsanto's competitors to use the data. After a full trial on the merits, the district court held that the particular 1978 amendments to FIFRA which mandated this result violate the Taking Clause of the Fifth Amendment to the Constitution. This is a direct appeal from the court's final judgment enjoining EPA from implementing these use and disclosure provisions.

### A. The FIFRA Amendments At Issue.

FIFRA provides that before any pesticide may be sold or distributed in the United States, EPA must register the pesticide and approve its composition and label. J.S. App. 7a. The label must contain, among other information, the name and percentage of each active ingredient; the total percentage of all inert ingredients; the uses for which the pesticide may be sold and directions for these uses; and all necessary warnings, hazard statements and limitations on use. Id. at 7a-8a; 7 U.S.C. § 136a(c)(1)(1982); 40 C.F.R. § 162.10 (1983). Before approving an application for registration, EPA must determine that the pesticide "will perform its intended function without unreasonable adverse effects on the environment" and that "its composition is such as to warrant the proposed claims for it." 7 U.S.C. § 136a(c)(5)(1982).

Since FIFRA's enactment in 1947, applicants have supported their pesticide registrations by submitting research and test data that often included valuable trade secrets they had developed. From 1947 until the 1978 FIFRA amendments, the confidentiality of these trade secrets was preserved.<sup>6</sup> Al-

<sup>\*</sup>J.S. App. 26a-27a; J.A. 63-65, 84-85, 96; 7 C.F.R. § 1.3(b)(1)(1949); 7 C.F.R. § 1.4(b)(15)(1962); 7 C.F.R. § 1.4(b)(15)(1967); Exec. Order No. 11222, § 205, 30 Fed. Reg. 6469 (1965).

though not mentioned by EPA, agency disclosure of the trade secrets would have been an offense under the Trade Secrets Act, 18 U.S.C. § 1905 (1982). It was also the policy of the United States Department of Agriculture (USDA), which administered FIFRA before EPA, that research and test data submitted by one company in order to obtain a registration could not be used by another company for registration purposes without the data submitter's consent.

Congress reaffirmed this historic protection of trade secrets in 1972, two years after EPA began administering FIFRA. In response to concerns that EPA was seeking to abandon this protection, the 1972 amendments expressly prohibited EPA from disclosing trade secrets and from granting a registration to one company on the basis of another's trade secrets unless the trade secret owner had first agreed. See Federal Environ-

<sup>&</sup>lt;sup>7</sup> There is no basis for EPA's claim that one of the district court's findings of fact is clearly erroneous. EPA Brief at 8 n.8, 30 Former Directors of USDA's Pesticide Regulation Division testified that USDA's "policy, from the very beginning" was that data submitted to register a pesticide "belonged to one individual registrant [and] was not to be used by another unless he had permission." J.A. 85; id. at 60-62. The Chief Staff Officer for Human Safety in USDA (and the EPA), who supervised the employees engaged in the registration process, confirmed that this was the policy. Id. 63-65. There is thus more than substantial evidence to support the district court's finding that USDA's "policy" when it administered FIFRA was that data submitted by one company could not be used to support the registration of another company's pesticide without permission of the data submitter. J.S. App. 26a. See Inwood Laboratories, Inc. v. Ives Laboratories, Inc., 456 U.S. 844, 855-58 (1982). The testimony EPA relies upon shows at most that some USDA employees might have violated USDA's policy. "Interpretation 18," which EPA also cites, is merely a USDA regulation setting forth the information to be contained on labels of common pesticides. See Interpretation with Respect to Warning, Caution and Antidote Statements Required to Appear on Labels of Economic Poisons, 27 Fed. Reg. 2267 (1962). It neither states nor purports to state USDA's policy on "piggyback" registrations, a policy that the Pesticide Regulation Division Directors established. J.A. 85. The evidence at trial here also showed Monsanto did not know that after EPA began administering FIFRA, one company used Monsanto's data for registration purposes. J.A. 232.

mental Pesticide Control Act of 1972, Pub. L. No. 92-516, 86 Stat. 973, 979-80 (1972). Contrary to EPA's suggestion (EPA Brief at 10-11, 31), in protecting trade secrets Congress itself adopted "the definition of 'trade secret' as incorporated in the RESTATEMENT OF TORTS [§ 757]." S. Rep. No. 838 (Part II), 92d Cong., 2d Sess. 72 (1972). A series of judicial decisions subsequently compelled EPA to accept the Restatement definition, which it had strenuously opposed. See, e.g., Mobay Chemical Co. v. Costle, 447 F. Supp. 811, 825 (W.D. Mo. 1978); Chevron Chemical Co. v. Costle, 443 F. Supp. 1024, 1031-32 (N.D. Cal. 1978).

When Congress amended FIFRA in 1978, it enacted the disclosure and use provisions found unconstitutional in this case. Amended Sections 10(b) and (d) and the last sentence of amended Section 3(c)(2)(A) drastically altered FIFRA by removing the former prohibitions against EPA's divulging of trade secrets. Instead of preserving the confidentiality of a company's research and test data submitted with its registration application, the amended provisions direct EPA to make such data "available for disclosure to the public" within 30 days after registering the pesticide. 7 U.S.C. §§ 136a(c)(2)(A), 136h(d)(1)(1982). The record in this case demonstrates that

<sup>&</sup>lt;sup>8</sup> See also Amchem Products, Inc. v. GAF Corp., 594 F.2d 470 (5th Cir. 1979); Dow Chemical Co. v. Costle, No. 76-10087 (E.D. Mich. Nov. 16, 1977); Mobay Chemical Corp. v. Train, 394 F. Supp. 1342 (W.D. Mo. 1975). EPA initially refused to follow the Restatement definition of trade secrets (Trial Exh. 29), and during oversight hearings, was severely chastised for being "bitterly opposed" to the statutory prohibitions regarding the disclosure and use of trade secrets. FEPCA Implementation: Hearings Before the House Agriculture Comm., 93d Cong., 1st Sess. 11-12 (1973) (Rep. Poage, Chmn.). EPA nevertheless began automatically rejecting all claims of trade secret protection until the decisions cited above halted this practice.

Contrary to EPA's suggestion (EPA Brief at 10), the 1975 FIFRA amendments did not address the question whether trade secrets in pre-1970 data could be "used in considering another application." Mobay Chemical Corp. v. Costle, 439 U.S. 320 (1979).

Throughout this litigation EPA has been prohibited from disclosing Monsanto's trade secrets or allowing them to be used by competitors. Trial [Footnote continued]

Monsanto's competitors can and would receive Monsanto's trade secrets through these provisions. J.A. 218, 253-54; Trial Exh. 14. Although amended Section 10 does provide a narrow exemption from disclosure of product formulas and manufacturing processes, and amended Section 10(g) prohibits EPA from "knowingly" disclosing a registrant's data to a foreign or multinational pesticide producer, the record further reveals that these limited measures would not effectively forestall disclosure of virtually all of Monsanto's trade secrets. <sup>10</sup>

The 1978 amendments also removed the requirement that an applicant obtain the permission of a trade secret owner in order to use the trade secret to support registration. If the applicant's pesticide contains ingredients similar to those in products registered by other producers, the applicant may rely on the trade secrets submitted by its competitors without conducting any research of its own and procure what is commonly

Exhs. 47 and 50. See Justice Blackmun's opinion denying EPA's stay application. Mot. Aff., App. A. Nevertheless, Monsanto has continued to be threatened with the disclosure and use of its trade secrets, especially by several EPA lapses which have resulted in disclosures. For example, EPA revealed certain Monsanto test data to a private attorney on May 7, 1982, and to Pesticide and Toxic Chemical News for a story appearing June 15, 1983. After the first incident, the district court ordered EPA to show cause why its Administrator should not be held in contempt; on August 31, 1982, EPA consented to an order further restricting its treatment of Monsanto's trade secrets.

<sup>10</sup> EPA's own expert testified at trial that the exemption for product formulas and manufacturing processes would apply to only a minute fraction of the trade secrets Monsanto has submitted. See J.A. 256-58. Even for that fraction, Sections 10(b) and 10(d)(1) permit disclosure based on generalized findings by the Administrator. 7 U.S.C. §§ 136h(b), 136h(d)(1)(1982). The Section 10(g) limitation, when it applies, simply requires recipients to "affirm" that they do not presently intend to deliver or sell the disclosed information to a foreign or multinational producer. 7 U.S.C. § 136h(g)(1)(1982). Apart from loopholes EPA has acknowledged, see page 33 & note 45 infra, no provisions exist for monitoring and enforcing the affirmation. Despite the affirmation, foreign companies already have sought Monsanto's trade secrets under Section 10. See Tr. 632-34; J.A. 75-76 (reprinting form affirmation).

known as a "me-too" or "piggyback" registration for its competing product. 7 U.S.C. § 136a(c)(1)(D)(1982).

Recognizing that the use provision would deprive companies of valuable property in the form of trade secrets. Congress created a limited private compensation scheme for trade secrets submitted after 1969. 7 U.S.C. § 136a(c)(1)(D)(ii)(1982); S. Rep. No. 334, 95th Cong., 1st Sess. 31 (1977). Those competitors who use another's research and test data to register domestic pesticides must, in certain instances, offer compensation to the property owner. S. Rep. No. 334 at 31; 7 U.S.C. § 136a(c)(1)(D)(1982). If the offer is unacceptable, the owner must submit to binding arbitration. If he does not, the "piggyback" applicant obtains the registration and the owner forfeits the right to any compensation. 7 U.S.C. § 136a(c)(1)(D)(ii)(1982). The amendments provide no standards for determining the amount of compensation (45 Fed. Reg. 55394 (1980)(FMCS notice); J.S. App. 21a, 34a) and EPA informed Congress that EPA had no expertise to set such standards. S. Rep. No. 334, at 72.11

Although companies that acknowledge reliance upon data disclosed under Section 10 to register their pesticides must offer compensation, there is no such requirement for competitors who use the data to generate their own registration mate-

The private arbitrators appointed pursuant to Section 3(c)(1)(D) have essentially unreviewable power. The Federal Mediation and Conciliation Service (FMCS) has decided not to promulgate substantive standards for arbitrating FIFRA disputes and FMCS's view is that Section 3(c)(1)(D) and its legislative history "illustrate the difficulty of establishing a comprehensive set of substantive standards." 45 Fed. Reg. 28105, 28107 (April 28, 1980). FMCS "rarely arranges or conducts arbitration of commercial disputes." 45 Fed. Reg. at 28106; id. at 55395 (Aug. 19, 1980). The "private labor arbitrators [on its roster] do not handle commercial disputes such as the compensation disputes arising under FIFRA." Id. at 28106. Consequently, arbitrations under Section 3(c)(1)(D) are conducted under the auspices of the American Arbitration Association (AAA), and FMCS makes its appointments from AAA's panel of commercial arbitrators. 29 C.F.R. § 1440.1 (1982); 45 Fed. Reg. at 28106.

rial or who use the data outside the FIFRA registration process. Such competitors are free to do with the data as they please and to obtain whatever advantage they can without compensating the trade secret owner for his property. <sup>12</sup> None of the 1978 FIFRA amendments provides that the federal government must compensate the trade secret owner for the loss of his property.

## B. The Effect Of The District Court's Injunction.

Although the constitutional issues presented here arise in the context of an environmental regulatory statute, this is not a health and safety case. Instead, it is a case of first impression involving the protection of trade secrets under the Fifth Amendment. The district court's limited injunction protecting Monsanto's trade secret property does not impair EPA's ability to make health and safety determinations. See J.S. App. 42a-43a. Monsanto has never challenged the provisions in FIF-RA requiring applicants to submit adequate information to justify registration.

The disclosure provisions, which the district court enjoined, are at best ancillary to EPA's scientific review process. It is, of course, EPA's responsibility to review and evaluate the data supporting registration applications, and EPA has not contended that it requires assistance from the public to fulfill this responsibility. See, e.g., EPA Brief at 24-26. In any event, EPA does not get such assistance from the 1978 amendments since the disclosure provisions do not make information available until after EPA grants a registration. 7 U.S.C. § 136a(c)(2)(A)(1982). To the extent EPA needs expert outside advice, EPA can and does seek it on a confidential basis from scientific consultants pursuant to Section 21 of FIFRA. In addition, the agency regularly obtains expert technical review

<sup>&</sup>lt;sup>12</sup> In addition, no compensation is required for use of data submitted before 1970, for any data fifteen years after submission, or for competitors' private use of the data for purposes other than domestic "piggyback" pesticide registrations. 7 U.S.C. § 136a(c)(1)(D)(iii)(1982).

from the FIFRA Scientific Advisory Panel and its appointees under FIFRA § 25(d). 7 U.S.C. §§ 136s, 136w(d)(1982). See J.S. App. 24a-25a.

The data use provision does not advance safety and in fact reduces the scientific foundation available for EPA to evaluate the safety of "piggyback" pesticides. Applicants, not EPA, decide whether to undertake their own research and testing or to rely on their competitor's data. 13 Thus, FIFRA's use provision merely facilitates a competitor's interest in obtaining registration: the provision does not contribute to the agency's safety evaluation. Without this provision, competing companies would test and research their potential products. Such research and testing would independently establish the safety and efficacy of subsequent pesticides and serve as a check on the validity of research and test data submitted on similar pesticides registered previously. The 1978 amendments eliminated this check by allowing a competitor's products to be marketed solely on the basis of the first registrant's research and testing.14

In short, despite the district court's injunction and Circuit Justice Blackmun's denial of EPA's request for a stay, <sup>15</sup> EPA remains free to grant, deny, cancel and suspend pesticide registrations. See also 48 Fed. Reg. 32012 (1983) (announcing

<sup>&</sup>lt;sup>13</sup> See National Agricultural Chemicals Association v. EPA, 554 F. Supp. 1209 (D.D.C. 1983) (invalidating 40 C.F.R. § 162.9-4, 5 (1979) and 47 Fed. Reg. 57635 (1982)) (not appealed by EPA).

<sup>&</sup>lt;sup>14</sup> Some amici supporting EPA argue that disclosure is necessary so that interested third parties can replicate the research and test data to confirm its validity. Other amici (and EPA) argue that the use provision is necessary to avoid such replication because it is wasteful and duplicative. Contrast Brief of the American Ass'n for the Advancement of Science et al., as Amicus Curiae and Brief of the Pesticide Producers Ass'n et al., as Amici Curiae. See also Appendix B to Monsanto's Brief in Opposition to EPA's Application for a Stay Pending Appeal (July 11, 1983).

<sup>&</sup>lt;sup>18</sup> Circuit Justice Blackmun denied EPA's application on July 27, 1983, with a written opinion included as Appendix A to the Motion to Affirm.

EPA Pest. Reg. Notice 83-4, at 1) ("the Agency will remain free to evaluate all relevant data in its files").

#### SUMMARY OF ARGUMENT

Monsanto's trade secrets constitute private property within the meaning of the Taking Clause. EPA conceded as much when it stipulated that Monsanto's trade secrets were property. The district court held only that because the FIFRA use and disclosure provisions take Monsanto's property in violation of the Taking Clause, the provisions could not be considered a valid regulation of interstate commerce. EPA proposes that in deciding whether the FIFRA amendments take private property for a public use in violation of the Fifth Amendment, the Court should employ a traditional Commerce Clause analysis by balancing the private interest destroyed against the public interest advanced by the legislation. EPA's balancing test, however, conflicts with the Fifth Amendment, which permits takings only for a "public use" but nevertheless requires "just compensation" regardless of how strong (or weak) the policies underlying the legislation happen to be.

The Framers of the Fifth Amendment defined property to include not only physical things, but other products of man's labor and invention. Gaining meaning from experience, the term "property" in the Fifth Amendment includes intangible property. Today the recognition of trade secrets as property is critically important to American industry and to the continued technological growth that is transforming the American economy.

Trade secrets are therefore recognized as property under state and federal law, including the Internal Revenue Code. The law of Missouri, where Monsanto is based, and the law of the other states, is that trade secrets are like other forms of property which an owner can sell, license, assign or devise. EPA's claim that trade secrets are not property is contrary to existing rules and understandings, including the understanding of the Department of Justice. As the Court has held, it is

such rules and understandings that determine the meaning of property under the Fifth Amendment.

Monsanto's trade secrets are valuable property and have resulted from an enormous expenditure of time, money and effort. Throughout the pesticide industry, an average of 20,000 chemical compounds must be synthesized and screened before one is found that has the potential for becoming a commercially viable pesticide. The research, testing, and development of potential new pesticides is fraught with many risks. Monsanto's research and test data contain trade secrets that the company uses to discover new pesticides at the rate of 1 in every 10,000 compounds synthesized and screened, which is well above the industry average. Because these trade secrets are extraordinarily valuable, Monsanto keeps the data containing them under lock and key. If Monsanto's trade secrets were not protected, competitors could use them to destroy Monsanto's hard-earned innovative advantages.

EPA's argument that Monsanto's trade secrets are not "property" because Congress legislated them out of existence is contrary to the legislative history of FIFRA. The 1978 FIFRA amendments instead reflect Congress' view that companies such as Monsanto have a continuing proprietary interest in their trade secret data after it has been submitted to EPA. Even if Congress had intended to do so, it cannot preempt the Fifth Amendment and has no power to define "property" for purposes of the Taking Clause. Otherwise, such takings could always be considered a mere redefinition of property. So long as the Fifth Amendment stands. Congress cannot thus make the relinquishment of property a condition of engaging in interstate commerce. EPA's further argument that FIF-RA defines the duties of a federal agency is irrelevant to whether Monsanto's trade secrets constitute property. Monsanto's reasonable expectations are derived not from FIFRA, as EPA asserts, but from state law and the rules and understandings that define property under the Fifth Amendment.

II. The FIFRA use and disclosure provisions take Monsanto's trade secret property. For trade secret owners, the

essence of their property is their right to exclude, which encompasses their right to use their property in secret and to prevent others from obtaining their trade secrets except through independent development. The practical effect of the FIFRA amendments, however, is to open Monsanto's research files to the world and to deliver the benefits of its hard-earned trade secrets to its competitors. To disclose trade secrets as FIFRA demands is to destroy this property. Congress itself recognized that it was taking property, which is why it required private compensation in arbitration proceedings whenever a competitor benefited by using another company's data to register a competing pesticide. Moreover, the FIFRA amendments destroy property by transferring it to the public and thereby requiring Monsanto to share it with others. The Fifth Amendment stands as a barrier against such a transformation of private property. While EPA once again invites the Court to employ a balancing test for determining whether a taking has occurred, the Taking Clause rejects the notion that whether property has been taken depends upon the strength of the policies behind the legislation. EPA's further claim that Monsanto "retains rights" to its trade secret property despite FIFRA is inaccurate. When trade secrets are disclosed, they become worthless as property. Only a fool would pay Monsanto for something EPA gives away under FIFRA.

"Just compensation" is not provided for the taking of III. Monsanto's trade secret property. Congress intended the FIF-RA private arbitration scheme to be the sole means of compensating owners for their property but that scheme does not provide just compensation, as EPA recognizes. Unlike the statute in the Regional Rail Reorganization Act Cases, 419 U.S. 102 (1974), a Tucker Act remedy would be inconsistent with FIFRA and its legislative history. The question is therefore not whether Congress intended to withdraw a remedy otherwise consistent with the legislation. Moreover, pursuant to the Congressional Budget Act of 1974, Congress determined the FIFRA amendments would not result in additional costs from Claims Court judgments for takings. Congress did not make such a determination in passing the Regional Rail Act of 1973.

IV. The FIFRA use provision takes property for a private use, which the Fifth Amendment prohibits regardless of whether just compensation is provided. As the Court has recognized, transfers of property from one competitor to another must be carefully scrutinized. The fact that such transfers are intended to benefit private competition only begins the inquiry. Congress may promote competition in many ways, but transferring one party's property to another in order to create a new competitor is not one of them.

### ARGUMENT

EPA opens with an elaborate argument that the FIFRA amendments at issue here were within Congress' power under the Commerce Clause. EPA Brief at 19-26. Monsanto follows a different course. The district court held only that legislation violating the Taking Clause of the Fifth Amendment is an invalid regulation of interstate commerce (see J.S. App. 33a), not that Congress had otherwise exceeded its Commerce Clause authority. The following discussion therefore begins with the Fifth Amendment.

I. MONSANTO'S TRADE SECRETS ARE "PRIVATE PROPERTY" WITHIN THE MEANING OF THE TAK-ING CLAUSE.

#### A. Introduction.

With respect to the Fifth Amendment, EPA's contentions differ little from its arguments regarding the Commerce Clause. According to EPA, the 1978 FIFRA use and disclosure provisions do not violate the Taking Clause because Congress struck a proper balance between private rights and the public welfare. EPA thus boldly proclaims that Monsanto's interests in its trade secrets are "insubstantial" compared to "the public interest served by the legislation" and that even the "total destruction" of Monsanto's trade secrets "should count for little when reckoned against the public interest served by the legislation." EPA Brief at 34-35.

This theme, which EPA repeats throughout its presentation, see, e.g., id. at 18, 38-40, reflects a line of argument that "has been universally rejects d" —namely, that the proper method of analysis under the Taking Clause is to balance the private interest destroyed against the public interest promoted by the governmental action. Kaiser Aetna v. United States, 444 U.S. 164, 174 (1979). As this Court has recognized, the position advocated by EPA would emasculate the Taking Clause for the quite apparent reason that legitimate governmental purposes are almost invariably deemed of more public importance than the superseded private use. See, e.g., United States v. Security Industrial Bank, 103 S. Ct. 407, 410 (1982); Loretto v. Teleprompter Manhattan CATV Corp., 458 U.S. 419, 425 (1982); Louisville Joint Stock Land Bank v. Radford, 295 U.S. 555, 602 (1935).

The Taking Clause assumes the point that EPA belabors: the government can take property only for a "public use." Whether the government has confiscated property depends not at all on the strength—or weakness—of the public policy underlying the legislation authorizing this result. The Taking Clause focuses instead on whether the owner has been deprived of his property. Throughout its brief EPA, in the words of Justice Holmes, seems to have "forg[otten] that a strong public desire to improve the public condition is not enough to warrant achieving the desire by a shorter cut than the constitutional way of paying for the change." Pennsylvania Coal Co. v. Mahon, 260 U.S. 393, 416 (1922).

# B. The Term "Property" In The Taking Clause Includes Trade Secrets.

EPA conceded early in this lawsuit that the research and test data Monsanto has submitted when registering its pesticides under FIFRA "contains or relates to trade secrets as defined by the Restatement of Torts" and that "Monsanto has

<sup>&</sup>lt;sup>16</sup> Sax, Takings and the Police Power, 74 Yale L.J. 36, 62 (1964). See also page 32 & note 44 infra.

certain property rights in its information, research and test data... which may be protected by the Fifth Amendment." J.A. 36, 58 (emphasis added). This stipulation binds EPA despite its argument in this Court that Monsanto has no such property rights and that the Fifth Amendment is therefore simply inapplicable. Moreover, the history and purposes of the Taking Clause demonstrate not only that Monsanto's trade secrets are indeed "private property," but also that Congress did not and was not free to legislate Monsanto's property out of existence, as EPA claims the FIFRA amendments have done in this case.

When the Framers provided in the Fifth Amendment that "private property" shall not "be taken for public use without just compensation," they secured for the citizens of this nation one of the most fundamental civil rights. See Lunch v. Household Finance Corp., 405 U.S. 538, 552 (1972). To Madison, 17 as to the other Framers, "property" was a "broad and majestic" term. Board of Regents v. Roth, 408 U.S. 564, 571 (1972); see Webb's Fabulous Pharmacies, Inc. v. Beckwith, 449 U.S. 155, 161 (1980) (citing Roth). Shortly after the Fifth Amendment had been adopted. Madison wrote that property shall not be taken "even for public use without indemnification of the owner" and that in "its larger and juster meaning" the term property "embraces everything to which a man may attach a value and have a right." 6J. Madison, Essay on Property in Writings 101, 103 (Hunt ed. 1906). Madison and his contemporaries firmly endorsed the influential views of John Locke that the "products" of a man's labor were his "property." J. Locke, The Second Treatise of Government, ch. 5, in Two Treatises of Government (1968). Encompassing more than just land or

<sup>17</sup> As originally introduced by Madison, the author of the Bill of Rights (see 1 B. Schwartz, The Bill of Rights: A Documentary History 3 (1971); L. Levy, The Origins of the Fifth Amendment 421-22 (1968)), the Clause read: "No person shall be . . . obliged to relinquish his property, where it may be necessary for public use, without a just compensation." Speech of James Madison, June 8, 1789, I Annals of Congress 434.

goods, property thus included whatever could be produced through "labour and invention."  $^{18}$ 

Trade secrets fit comfortably within the understanding of the Framers and of this Court. "Private property," of course, now includes both tangible and intangible property. See, e.g., United States v. Security Industrial Bank, 103 S. Ct. 407 (1982); Armstrong v. United States, 364 U.S. 40 (1960); United States v. General Motors Corp., 333 U.S. 373 (1945), See also Logan v. Zimmerman Brush Co., 455 U.S. 422, 430 (1982) ("the types of interests protected as 'property' are varied and. as often as not, intangible, relating 'to the whole domain of social and economic fact' "). Whether defined as a secret formula, pattern or device used in one's business (Restatement of Torts § 757, comment b (1939)) or as Judge Friendly held, "in the broad sense of any unpatented idea which may be used for industrial or commercial purposes,"19 Monsanto's trade secrets in its research and test data are plainly the product of labor. ingenuity and the expenditure of money and must be considered property.

But Monsanto does not rest on history alone, for the term "property" in the Fifth Amendment must "gather meaning from experience." Board of Regents v. Roth, 408 U.S. at 571 (quoting National Mutual Insurance Co. v. Tidewater Transfer Co., 337 U.S. 582, 646-47 (1949)(Frankfurter, J., dissenting)). The dramatic technological changes that have occurred since World War II, and the consequent transformation of the American economy, have rendered property such as trade secrets far more valuable and important to the continued viability of enterprises than could have been supposed two

<sup>&</sup>lt;sup>18</sup> 2 W. Blackstone, Commentaries \*405 (citing John Locke). Jefferson also adopted the Lockean view that a man's "property was whatever he produced by dint of his personal labor." Katz, Thomas Jefferson and the Right to Property in Revolutionary America, 19 J. Law & Econ. 467, 474 (1976).

<sup>&</sup>lt;sup>19</sup> Painton & Co. v. Bourns, Inc., 442 F.2d 216, 222 n.2 (2d Cir. 1971), cited and relied upon in Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470, 484 (1974). The Court in Kewanee also cited the "widely relied-upon" Restatement definition. 416 U.S. at 474-75.

centuries ago. Today the largest investment of many companies is in the creation and maintenance of such data and it is scarcely surprising that "the stock of intangible capital" derived from research and development "by Fortune 500 firms is estimated at \$47.8 billion."<sup>20</sup>

The states and the judiciary, as well as the federal government, have therefore recognized that trade secrets constitute valuable property and are to be treated as such. Both state and federal courts view trade secrets as property. A trade secret, like other forms of property, is assignable. When it is sold, the owner has "transferred property in the secret process." Fowle

<sup>&</sup>lt;sup>20</sup> Hirschey, Intangible Capital Aspects of Advertising and R&D Expenditures, 30 J. Indus. Econ. 375, 387 (1982); see, e.g., Clarkson, Intangible Capital and Rates of Return (American Enterprise Inst. 1977); Grabowski & Mueller, Industrial Research and Development, Intangible Capital Stocks and Firm Profit Rates, 9 Bell J. Econ. 328 (1978).

<sup>21</sup> See, e.g., In re the Iowa Freedom of Information Council and Des Moines Register and Tribune Co., No. 83-1573, slip op. at 1, 5-6, 11 (8th Cir. Dec. 30, 1983); Allan-Qualley Co. v. Shellmar Products Co., 31 F.2d 293, 296 (N.D. Ill. 1927), aff'd, 36 F.2d 623 (7th Cir. 1929); Anaconda Co. v. Metric Tool & Die, 485 F. Supp. 410, 425-26 (E.D. Pa. 1980); United States v. International Business Machs. Corp., 67 F.R.D. 40, 45 (S.D.N.Y. 1975); Stalker Corp. v. United States, 209 F. Supp. 30, 33 (E.D. Mich., 1962); Kelite Corp. v. Khem Chems. Inc., 162 F. Supp. 332, 337 (N.D. Ill. 1958); Continental Car-Na-Var Corp. v. Moseley, 148 P.2d 9, 12 (Cal. 1944); Town & Country House & Homes Serv., Inc. v. Evans, 189 A.2d 390, 393-94 (Conn. 1963); Data Gen. Corp. v. Digital Computer Controls, Inc., 188 U.S.P.Q. 276, 280 (Del. 1975); Donahue v. Permacel Tape Corp., 127 N.E.2d 235, 240 (Ind. 1955); Homer v. Crown Cork & Seal Co., 141 A. 425, 431 (Md. 1928); Wireless Specialty Apparatus Co. v. Mica Condenser Co., 131 N.E. 307, 310 (Mass. 1921); Glucol Mfg. Co. v. Schulist, 214 N.W. 152, 153 (Mich. 1927); Pomeroy Ink Co. v. Pomeroy, 78 A. 698, 699 (N.J. 1910); Drake v. Herrman, 185 N.E. 685, 686 (N.Y. 1933); Wexler v. Greenberg, 160 A.2d 430, 437 (Pa. 1960); McClary v. Hubbard, 122 A. 469, 473 (Vt. 1923). See generally 1 R. Milgrim, Trade Secrets § 1.01[2] at p. 1-7 & n.15 (1983) (collecting cases).

<sup>&</sup>lt;sup>22</sup> E.g., Dr. Miles Medical Co. v. John D. Park & Sons Co., 220 U.S. 373, 401-02 (1911); Painton & Co. v. Bourns, Inc., 442 F.2d at 225; Grand Rapids Wood Finishing Co. v. Hatt, 115 N.W. 714 (Mich. 1908); Larx Co. v. Nicol, 28 N.W.2d 705 (Minn. 1947); Tuttle v. Blow, 75 S.W. 617 (Mo. 1903); see 1 R. Milgrim, Trade Secrets § 1.02 (1983) (collecting other examples).

v. Park, 131 U.S. 88, 98 (1889). Like other types of property, a trade secret can form the res of a trust<sup>25</sup> and passes to a trustee in bankruptcy. Federal criminal liability may be imposed for the theft of trade secrets, and many states have enacted statutes specifically directed to this property offense. EPA's position, moreover, would come as quite a surprise to the Internal Revenue Service, for trade secrets have long been regarded as property under the Internal Revenue Code.

<sup>&</sup>lt;sup>25</sup> Restatement (Second) of Trusts § 82, comment e (1959); 1 A. Scott, *The Law of Trusts* § 82.5 at 703 (3d ed. 1967); see Green v. Folgham, 1 Sim. & St. 398, 57 Eng. Rep. 159 (1823).

<sup>&</sup>lt;sup>24</sup> See In re Uniservices, Inc., 517 F.2d 492, 496-97 (7th Cir. 1975); In re Bettinger Corp., 197 F. Supp. 273 (D. Mass. 1961), vacated on other grounds sub nom. Walker Mfg. Co. v. Bloomberg, 298 F.2d 688 (1st Cir. 1962); In re Keene, 2 Ch. 475 (1865); 1 A. Scott, The Law of Trusts § 82.5 at 407 (3d ed. 1967).

<sup>&</sup>lt;sup>25</sup> The National Stolen Property Act, 18 U.S.C. § 2314 (1982), in particular, treats trade secrets as property and has been applied to punish their theft. See, e.g., United States v. Seagraves, 265 F.2d 876 (3d Cir. 1959)(theft of geographical maps); United States v. Lester, 282 F.2d 750 (3d Cir. 1960)(same), cert. denied, 364 U.S. 937 (1961); United States v. Greenwald, 479 F.2d 320 (6th Cir.) (documents containing secret chemical formulations), cert. denied, 414 U.S. 854 (1973); United States v. Bottone, 365 F.2d 389 (2d Cir.)(Friendly, J.)(documents describing a secret manufacturing process), cert. denied, 385 U.S. 974 (1966). Cf. Perrin v. United States, 444 U.S. 37 (1979) (geological trade secrets). See also 18 U.S.C. § 1905 (1982) (prohibiting federal employees from disclosing trade secrets).

<sup>&</sup>lt;sup>26</sup> More than twenty states have enacted laws making appropriation or unauthorized disclosure of trade secrets a crime. See Stamicarbon, N.V. v. American Cyanamid Co., 506 F.2d 532, 540 n.11 (2d Cir. 1974)(listing statutes); 1 R. Milgrim, Trade Secrets § 1.10 (1983) (same).

<sup>27 &</sup>quot;The right of property in industrial knowledge has long been recognized by [the Tax] Court," United States Mineral Prods. Co. v. Commissioner, 52 T.C. 177, 196-97 (1969). Under the Internal Revenue Code, "[i]t is well settled that secret processes may constitute property and be dealt with contractually as such." Nelson v. Commissioner, 203 F.2d 1, 6 (6th Cir. 1953); Commercial Solvents Corp. v. Commissioner, 42 T.C. 455, 467 (1964). The Code defines "capital asset" as "property held by the taxpayer." 26 U.S.C. § 1221. Since trade secrets are property, payments received upon the sale of trade secrets are treated as capital gains. See, e.g., Ofria v. Commis-[Footnote continued]

In Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470, 486 (1974), the Court recognized that without legal protection of trade secrets, "organized scientific and technological research could become fragmented, and society as a whole, would suffer." Thus, trade secret law promotes "the efficient operation of industry" and plays an important part "in the technological and scientific advancement of the Nation." Id. at 493. In language echoing the Framers' view of property, the Court in Kewanee pointed out that the protection of trade secrets "permits the individual inventor to reap the rewards of his labor." Id.

The law of Missouri, where Monsanto is based, is consistent with the nationwide understanding that trade secrets are property. Protecting both Monsanto's "rights to exclude others" from its trade secrets and the company's "right to prohibit disclosure of its data" (J.S. App. 31a), Missouri law reflects "existing rules or understandings... that secure certain benefits and that support claims of entitlement"—in short, the rules and understandings that determine property interests under the Fifth Amendment, as this Court held in Board of Regents v. Roth, 408 U.S. 564, 577 (1972), and Webb's

sioner, 77 T.C. 524 (1981)(sale of trade secrets to Air Force); Stalker Corp. v. United States, 209 F. Supp. 30 (E.D. Mich. 1962)(government conceded that trade secrets are property); Huckins v. United States, 1960-1 U.S. Tax Cas. (CCH) ¶ 9394 (S.D. Fla. 1960). Moreover, the Internal Revenue Service has ruled that trade secrets constitute property for purposes of a tax-free transfer to a corporation under Section 351 of the Code. See Rev. Rul. 64-56, 1964-1 C.B. 133, as amplified by Rev. Rul. 71-564, 1971-2 C.B. 179 (concluding that the term "property" for purposes of Section 351 includes anything qualifying as a secret process or formula without regard to whether it is patentable).

<sup>&</sup>lt;sup>28</sup> See, e.g., Ultra-Life Laboratories v. Eames, 221 S.W.2d 224, 233 (Mo. 1949); Godefroy Mfg. Co. v. Lady Lennox Co., 134 S.W.2d 140, 141 (Mo. 1939); Germo Mfg. Co. v. Combs, 240 S.W. 872, 881 (Mo. 1922). See also Bunting v. McDonnell Aircraft Corp., 185 U.S.P.Q. 698, 703 (Mo. 1975); House of Tools & Engineering, Inc. v. Price, 504 S.W.2d 157, 159 (Mo. 1973).

Fabulous Pharmacies, Inc. v. Beckwith, 449 U.S. 155, 161 (1980).29

EPA would have the Court upset these property interests and, as the 21st century approaches, announce for the first time that one of the most important products of this technological age is not "property" protected by the Fifth Amendment. Years ago the Department of Justice told Congress that "formulae, designs, drawings, research data, etc., which although set forth on pieces of paper, are significant not as records but as items of valuable property." United States Department of Justice, Attorney General's Memorandum on the Public Information Section of the Administrative Procedure Act 34 (1967). This view of the Department of Justice, not EPA's, reflects the existing rules and understandings that trade secrets are private property.<sup>30</sup>

<sup>&</sup>lt;sup>29</sup> In still another appeal to federal legislative power, EPA asserts that Monsanto's trade secrets are not property because "the proper functioning of the registration scheme depends upon uniform application to all data." EPA Brief at 28. It is difficult to comprehend how EPA's desire for symmetry bears on the meaning of property in the Taking Clause. Property rights are basically derived from state law and it is common for federal legislation to operate against a background of varying state laws. Moreover, in claiming that uniformity is desirable, EPA fails to point out any significant variation.

<sup>&</sup>lt;sup>30</sup> EPA quotes dictum in E.I. DuPont de Nemours Powder Co. v. Masland, 244 U.S. 100, 102 (1917), for the proposition that trade secrets are not property because "one policy" of trade secret law was to maintain ethical business dealings. EPA Brief at 29. In addition to the facts that Masland was decided prior to Erie R.R. v. Tompkins, 304 U.S. 64 (1938), and that in an earlier opinion the Court had treated trade secrets as property, Board of Trade v. Christie Grain & Stock Co., 198 U.S. 236, 250-53 (1905) (Holmes, J.), the dictum in Masland does not support EPA. The issue in Masland centered on a dispute about the disclosure of trade secrets during trial preparation. The Court said only that it was irrelevant whether trade secrets (and trademarks) were property: "the starting point for the present matter is not property or due process of law, but that the defendant stood in confidential relations with the plaintiffs, or one of them." 244 U.S. at 102. See, e.g., National Starch Prods., Inc. v. Polymer Indus., Inc., 79 N.Y.S.2d 357 (App. Div.), appeal denied, 81 N.Y.S.2d 278 (1948).

EPA similarly misapprehends the relevance of the Restatement of Torts § 757 (1939) definition of a "trade secret" and its explanatory comment a. See

[Footnote continued]

# C. Monsanto's Trade Secrets Are The Result Of An Enormous Commitment Of Time, Money And Effort.

As previously indicated, EPA's position in the district court was different from its position here. By stipulating that Monsanto had "property rights" in trade secrets embodied in research and test data, EPA not only conceded the issue it now contests, but also obviated any need for proof on this subject. See pages 14-15 supra. Nevertheless, the record developed on other issues is sufficient to demonstrate why EPA made this admission and why in the district court EPA accurately viewed Monsanto's trade secrets as property.

The record shows, for example, that Monsanto's development of its trade secrets has required a massive commitment of resources and energy. In 1981 alone, the company spent \$70 million in its quest for new and better pesticides. J.A. 133. Despite these efforts, Monsanto's latest new herbicide—Roundup®—came on the market nearly nine years ago. Although Monsanto has registered only ten new herbicides under FIFRA since 1956, its rate of success is comparatively high.<sup>31</sup>

EPA Brief at 29. Comment a simply describes the origins of trade secret protection and acknowledges the historic relationship to tort principles. This in no way detracts from the modern recognition of trade secrets as property. To the contrary, the Restatement definition is widely adopted in the decisions cited above holding that trade secrets are property as a matter of state law. See generally 1 R. Milgrim, Trade Secrets § 1.02 (1983)(collecting cases); see also id. at § 1.01[2]. The fact that misappropriation of a trade secret may be considered a tort no more lessens property rights in trade secrets than the fact that trespass is a tort renders real property unworthy of Fifth Amendment protection.

<sup>31</sup> Six of Monsanto's registered pesticides account for nearly all of the company's commercial success: Lasso\*, Roundup\*, Avadex\*, Avadex\*, BW, Ramrod\* and Randox\*, J.A. 112, 137-38. Throughout the world, very few new pesticides are introduced each year. In 1966, for example, there were only 28 new pesticides; by 1974, the number had fallen to 10. Goring, The Costs of Commercializing Pesticides, Int'l Conf. of Entomology, August 20, 1976, reprinted in Hearings on FIFRA Extension Before the Subcomm. on Agricultural Research and General Legislation of the Senate Comm. on Agriculture, Nutrition and Forestry, 95th Cong., 1st Sess. 254 (1977).

The reasons for this become clear when one considers how new pesticides are developed.

Today there are thousands of pesticides registered under FIFRA, but most of these are end-use or formulated products. containing an identical or similar "active ingredient" combined with similar "inert ingredients" to dilute, dissolve, stabilize or otherwise improve the performance of the final product. 22 The great innovations have been with respect to "manufacturinguse products," which are generally pure forms of active ingredients used to produce final, formulated products. J.S. App. 4a-5a. A company that undertakes basic research to devise such a new pesticide exposes itself to tremendous risks. Id. at 5a-6a. Any company that decides to engage in the development of new pesticides must assemble and organize a team of 150 to 500 highly trained scientists, provide research facilities and sophisticated equipment, and identify a widespread problem in agriculture that will continue to exist for the more than twenty years it may take the company to recoup its investment. J.A. 130-31; J.S. App. 5a-6a.

After identifying a problem, the company must devise "extremely efficient, unique and technically sound ways" of synthesizing and screening tens of thousands of new chemical compounds. J.S. App. 6a-7a. On the average, four to eight years will have passed and 20,000 compounds will have been synthesized and evaluated before the first potentially success-

<sup>&</sup>lt;sup>32</sup> Section 2(a)(1) of FIFRA, 7 U.S.C. § 136(a)(1)(1982), defines "active ingredient," in the case of pesticides other than plant regulators, defoliants and desiccants, as any "ingredient which will prevent, destroy, repel, or mitigate any pest." An "inert ingredient," under Section 2(m), 7 U.S.C. § 136(m)(1982), is "an ingredient which is not active."

<sup>&</sup>lt;sup>33</sup> Prior to the enactment of FIFRA in 1947, nearly all such "manufacturing-use products" had been discovered by the federal government as part of the war effort. Not until 1950, when Dow Chemical Company introduced "Premerge," did companies begin extensive marketing of "proprietary" pesticides containing active ingredients created by private research. J.A. 126-27. Monsanto is engaged in the development and production of both end-use and manufacturing-use pesticide products.

ful candidate is discovered. Id. at 5a; J.A. 132. Monsanto's superior research and testing techniques, however, have enabled it to become an industry leader in discovering potentially successful candidates on an average of 1 in every 10,000 compounds synthesized and screened. Id.

During the years of additional research that takes place between the identification of a commercial candidate and the anticipated initial marketing of the product, crop patterns may shift and weeds once prevalent may decline. J.A. 138-39; J.S. App. 5a. A product, if developed, may prove too expensive; further testing may indicate that environmental risks may result; or it may be impossible to provide the kind of consistent seasonal production that farmers require. J.A. 135-37. As a result, what once appeared to be a product worthy of development may be rejected as a "loser" after millions of dollars and years of effort have been expended.

In addition to these obstacles, it will take years to develop a feasible manufacturing process, construct a pilot plant, procure the capital needed and build adequate manufacturing facilities. J.A. 135. When a company does begin selling a new product, the return on investment must be substantial. The new pesticide must, of course, pay for the enormous costs incurred in developing it. J.A. 132. From 1960 through 1981, for example, Monsanto expended more than \$250,000,000 just in developing its relatively few successful pesticides. J.A. 142. But in marketing its new pesticide, a company must also recoup the losses incurred on the 19,999 losers. See J.A. 132.

<sup>&</sup>lt;sup>34</sup> One leading German company, for example, synthesized more than 94,000 compounds before coming up with its first commercial herbicide, which it now markets in the United States. J.A. 132. Monsanto discovered Roundup® 17 years after it began searching for a pesticide to control Johnson grass (J.A. 148); the product was not registered for crop use until 1976, 24 years after Monsanto began its search. *Id.* at 148-49. Monsanto "identified the target for which Lasso® was developed in the mid-1950's," did not obtain its initial registration for Lasso® until 1969, and still is engaged in substantial research aimed at expanding its uses. J.A. 45-46.

Generally, a total of 14 to 22 years will have passed from the time the company began synthesizing new chemicals until the resulting "product reaches a point where its costs of discovery, development and commercialization have been recovered." J.S. App. 5a.

In the course of researching and developing a new pesticide, the company will have conducted efficacy studies, phytotoxicity studies, metabolism and residue studies, environmental chemistry studies, toxicology studies, fish and wildlife studies, and manufacturing studies. J.S. App. 17a; J.A. 46-56, 144-47 (explaining the nature of such studies and their purpose). The resulting research and test data, and the trade secrets contained in it, must be furnished to EPA in order to register the pesticide under FIFRA. Over the years Monsanto has submitted such data and has thereby revealed to EPA, in confidence, the chemistry, metabolism, course of degradation, residues and interactions among ingredients of each pesticide Monsanto has developed. J.A. 144-47, 151-52.

These trade secrets are extraordinarily valuable, and their preservation is critical to the continuing viability of Monsanto's business. The company therefore maintains its research and test data under lock and key; employees are permitted access only on a need-to-know basis. Security guards are deployed around the clock and Monsanto personnel are required to execute security agreements respecting the data. J.A. 57, 147-48.

If Monsanto's research and test data were publicly released, the company would lose the innovative advantage gained through its research efforts. With Monsanto's trade secrets in hand, competitors could seek to reconstruct Monsanto's product formulas. J.A. 144-46; Tr. 192. Monsanto itself uses its trade secrets to improve the company's existing products and to develop new pesticides at a rate significantly above the industry average. J.A. 116; see page 23 supra. Monsanto has become a leader in sophisticated and unique technology that enables scientists to analyze particular molecules; information

revealing this secret technology developed by Monsanto is also contained within the research and test data the company has submitted to EPA. J.A. 141, 151-52. The metabolism studies on each Monsanto product, for example, enable the company to gain valuable "insights into how it works, what we should be doing to build the next molecule, and how . . . we make the present compound work better." J.A. 151. Monsanto's trade secrets provide important leads not only for discovering new pesticides, but also for expanding the uses of existing products, which is just as critical. J.A. 45-46. If the trade secrets Monsanto has submitted to EPA were disclosed, Monsanto's competitors would be able to obtain those leads for themselves (J.A. 102: Tr. 102, 256 (confidential)) as well as secure registrations of their pesticides in foreign countries and even register their competitive products for expanded uses in the United States.35

## D. EPA's Arguments That Monsanto's Trade Secrets Should Not Be Considered "Property" Conflict With The Taking Clause.

In light of the foregoing, it is remarkable for EPA now to contend that Monsanto's trade secrets are not property. In so arguing, EPA has failed to offer any coherent analysis of the meaning of "property" in the Taking Clause. Instead, it simply lists a variety of unrelated considerations that have little, if anything, to do with whether Monsanto has property rights in its trade secrets, a point EPA conceded in the lower court. Much of what EPA now has to say in this regard not only is irrelevant to the issue EPA purports to address, but also is in conflict with the function of the Taking Clause in our system of government.

Although apparently recognizing that Monsanto's trade secrets constituted property so long as the company did not use

<sup>&</sup>lt;sup>35</sup> J.S. App. 23a; J.A. 140-43. Monsanto competes not only with United States companies seeking to devise new pesticides, but also with companies in West Germany, Switzerland, the United Kingdom and Japan. J.A. 143.

them to register pesticides under FIFRA, EPA first contends that because Monsanto "chose to reveal" its data, the company "accepted the conditions" that the data would be disclosed and used by the company's competitors. EPA Brief at 27. It is unclear whether EPA is arguing that Congress intended to treat trade secrets submitted under FIFRA as something other than property or that Monsanto somehow "waived" its Fifth Amendment rights in the property. In either event, EPA's assertion, which it rests on the supremacy of federal legislation, is in error.

EPA cannot support its position by relying on FIFRA. The 1978 FIFRA amendments themselves reflect Congress' view that trade secrets in research and test data are property. When Congress amended the statute in 1978, it recognized that data developers like Monsanto had a continuing "proprietary interest" in their data after they furnished it to EPA, S. Rep. No. 334, 95th Cong., 1st Sess. 31 (1977), and were "entitled," in the words of the Conference Committee, to "compensation" because they "have legal ownership of the data." H.R. Rep. No. 1560, 95th Cong., 2d Sess. 29 (1978). Indeed, EPA informed Congress that the data "has a continuing commercial value beyond its value in achieving the immediate registration for which it was developed"; although consistent with the record in this case, EPA's statement contradicts what EPA now represents to this Court. \*\*

Congress thus knew full well that the owners of trade secrets had property interests in their data, interests that de-

<sup>\*\*</sup>Statement of Douglas M. Costle, Administrator, Environmental Protection Agency, in H.R. Rep. No. 343, 95th Cong., 1st Sess. 8 (1977); H.R. Rep. No. 663, 95th Cong., 1st Sess. 59 (1977); S. Rep. No. 334, 95th Cong., 1st Sess. 72 (1977). EPA's statement quoted in the text and its admission to both Houses of Congress that it had no expertise in determining the economic value of such research and test data (id., see also 123 Cong. Rec. 25710 (1977) (remarks of Sen. Leahy)), contrasts sharply with its unsupported statement to the Court that the "principal value of the data to Monsanto is the competitive advantage derived from obtaining a registration." EPA Brief at 31.

serve "just compensation," as the Senate floor leader stated when explaining the amendments to the Senate. 123 Cong. Rec. 25709 (1977)(remarks of Senator Leahy). But Congress incorrectly believed that "[d]etermining the amount and terms of such compensation are matters that do not require active governmental involvement. . . . The compensation payable should be determined to the fullest extent practicable, within the private sector." Id.

The point here is not that the Taking Clause rejects this treatment of private property, which it does, but that in the 1978 FIFRA amendments Congress did not attempt to remove trade secrets from the realm of "private property" and would not have had the power to do so in any event. EPA's suggestion otherwise is simply mistaken. Congress instead assumed that it could avoid having the federal government provide compensation for EPA's disclosure of trade secrets because it had set up a private compensation scheme relating to the use of such property for registering competitors' products. See S. Rep. No. 334, 95th Cong., 1st Sess. 41 (1977); H.R. Rep. No. 663, 95th Cong., 1st Sess. 18-19 (1977).

It is of course true, as EPA points out, that conflicting state laws must give way to federal statutes enacted pursuant to Congress' authority under the Commerce Clause. EPA fails to recognize, however, that while Congress may thereby preempt state law, it cannot preempt the Fifth Amendment. Justice Jackson made the point forcefully: "The very purpose of a Bill of Rights was to withdraw certain subjects from the vicissitudes of political controversy. . . . One's right to . . . property . . . may not be submitted to vote," West Virginia State Board of Education v. Barnette, 319 U.S. 624, 638 (1943). Monsanto's property rights may be "solely a question of federal law" (EPA Brief at 28), but that federal law is the Fifth Amendment, not FIFRA as EPA assumes."

<sup>37</sup> As Monsanto has argued, "[t]hough the meaning of property as used in . . . the Fifth Amendment is a federal question, it will normally obtain its [Footnote continued]

To hold otherwise would be to emasculate the Taking Clause. If Congress were the arbiter of the meaning of "private property" under the Taking Clause, federal legislation destroying property rights could always be considered a mere redefinition of property rather than a "taking." In light of the federal government's nearly unbounded capacity to regulate commerce, there would then be nothing to constrain Congress from using its legislative authority to promote the common good by forcing owners to sacrifice their property, including trade secrets. See Kaiser Aetna v. United States, 444 U.S. 164. 172 (1979). That is precisely the opposite of what the Framers intended, as the Court recognized in PruneYard Shopping Center v. Robins, 447 U.S. 74, 84 (1980), when it stated "Inlor as a general proposition is the United States, as opposed to the several States, possessed of residual authority that enables it to define 'property' in the first instance."

EPA's related claim that Monsanto's trade secrets are not property because the company "accepted the conditions" imposed by the 1978 FIFRA amendments (EPA Brief at 18, 27) does no more than state a theory. If Congress had the power to destroy Monsanto's trade secrets without just compensation, EPA's "waiver" argument would be unnecessary. If, as contended above, Congress did not have such power because of the Taking Clause, EPA's statement that Monsanto "consented" is merely fiction. Two things are certain. First, as EPA acknowledges in its regulations, the data at issue here was in no sense "voluntarily submitted." See 40 C.F.R. § 2.307(g)(1982)("no information to which this section applies is voluntarily submitted information"). Second, Monsanto no more accepted the destruction of its trade secret property by registering its pesticides than the building owner in Loretto v.

content by reference to local law." TVA v. Powelson, 319 U.S. 266, 279 (1943). Accord, United States v. Causby, 328 U.S. 256, 266 (1946).

Even state governments do "not have unlimited power to redefine property rights." Loretto v. Teleprompter Manhattan CATV Corp., 458 U.S. 419, 439 (1982). See also Webb's Fabulous Pharmacies, Inc. v. Beckwith, 449 U.S. 155, 164 (1980).

Teleprompter Manhattan CATV Corp., 458 U.S. 419 (1982), "consented" to a CATV installation by becoming a landlord subject to state regulation, than the petitioners in Armstrong v. United States, 364 U.S. 40 (1960), "accepted the condition" of having their right to assert a lien destroyed by supplying materials to the manufacturer of boats for the United States, or than the owner of mineral rights in Pennsylvania Coal Co. v. Mahon, 260 U.S. 393 (1922), "consented" to the regulations there at issue by choosing to engage in the coal mining business.

To accept EPA's consent theory would be to sanction any governmental regulation of business that destroys property. While EPA emphasizes that the FIFRA amendments still protect Monsanto's manufacturing processes and product formulas (EPA Brief at 17), its arguments would empower Congress to take even this property freely or, indeed, any other property that Monsanto owns. Contrary to EPA's position (EPA Brief at 18, 27), so long as the Fifth Amendment stands, the relinquishment of private property cannot be deemed a condition of engaging in interstate commerce.<sup>39</sup>

<sup>&</sup>lt;sup>39</sup> See L. Tribe, American Constitutional Law § 9-5, at 465 (1978) (pointing out the fallacy of the argument that government regulation may be upheld against a Taking Clause challenge by the mere device of characterizing the regulation as a "condition").

The courts have long recognized that the "Government cannot make a business dependent upon a permit and make an otherwise unconstitutional requirement a condition to the permit." Standard Airlines, Inc. v. CAB, 177 F.2d 18, 20 (D.C. Cir. 1949). Accord, Loretto v. Teleprompter Manhattan CATV Corp., 458 U.S. at 439 n.17 ("a landlord's ability to rent his property may not be conditioned on his forfeiting the right to compensation for a physical occupation"); Frost & Frost Trucking Co. v. Railroad Comm'n of Calif., 271 U.S. 583, 593 (1926) ("[i]n reality the carrier is given no choice... an option to forego a privilege which may be vital to his livelihood or to submit to a requirement which may constitute an intolerable burden"); Parks v. Watson, 716 F.2d 646 (9th Cir. 1983) (city's refusal to vacate platted streets unless plaintiff's geothermal wells were conveyed as exchange held to be an unconstitutional condition).

EPA's further contention that the legislation at issue here defines the "duties of a federal agency" (EPA Brief at 28) is irrelevant to the question whether Monsanto's trade secrets are property. A statute requiring a federal agency to confiscate a company's production facilities rests on no better footing than federal legislation directly ordering the company to relinquish its means of production. In neither instance does the nature of the regulation or the party to whom it is directed transform property into something outside the purview of the Taking Clause. Despite EPA's claims, it would make no difference under the Taking Clause if, instead of placing duties on EPA, FIFRA directly required Monsanto to unlock its research files so that any interested private citizen could browse or ordered Monsanto to mail its research and test data to rival firms so that they could register competing products.

This leaves only EPA's argument that prior to 1978, Monsanto had no "reasonable expectation" that Congress would refrain from requiring the use or disclosure of the company's data. EPA Brief at 29-32. Once again, it is far from clear how anything EPA states in this respect pertains to the constitutional issue EPA ostensibly addresses—whether Monsanto's trade secrets are "property" within the meaning of the Taking Clause. EPA's claim, for example, that "the 1978 Amendments requiring disclosure do not defeat an interest of independent significance" (EPA Brief at 32), itself lacks significance. While converting Monsanto's trade secrets into public information would have enormous financial significance for the company, this relates to the "taking" question, not whether Monsanto's trade secrets constituted property before they were so destroyed.

As shown above, Monsanto's "expectations" are derived not from FIFRA, but from its property rights under state law and "existing rules or understandings" that define property under the Fifth Amendment. 40 EPA's position that FIFRA creates

<sup>&</sup>lt;sup>40</sup> There is nothing to EPA's quarrel (EPA Brief at 8 n.8, 30 n.25) with the district court's finding that under the USDA's administration of FIFRA, trade secrets were fully protected. See page 4 & note 7 supra.

no expectations is thus beside the point. Congress does not have plenary authority to destroy Fifth Amendment expectations. In arguing otherwise, EPA merely restates its mistaken view of the preeminence of federal legislative power over rights in property protected by the Taking Clause. In this regard, it is frivolous for EPA to contend that the importance of trade secrets to Monsanto stems from the FIFRA licensing system, which EPA says Congress may freely modify. EPA Brief at 31-32. If FIFRA were repealed tomorrow, if registration of pesticides were no longer required, Monsanto most certainly would not unlock its files and throw open its trade secrets to the world. Research and testing at Monsanto would necessarily proceed and its trade secret property would continue to be protected; Monsanto could not otherwise survive. 41

#### II. THE 1978 FIFRA AMENDMENTS TAKE MONSANTO'S TRADE SECRET PROPERTY.

The use and disclosure provisions enacted in the 1978 FIF-RA amendments operate to "take" Monsanto's trade secret property according to well-established Fifth Amendment principles. Whether private property has been taken necessarily depends upon the nature of the property<sup>42</sup> and the owner's

<sup>&</sup>lt;sup>41</sup> Regardless of what federal legislation provided, the research and testing Monsanto conducts would be necessary to the development of any pesticide. There are, throughout the world, two basic conditions that a potential pesticide must meet before it can be considered commercially acceptable: the product must be effective in preventing damage by a pest and its use for the intended purpose must not cause harm to those applying the pesticide, to the product it is designed to protect, or to the environment. See F. McEwen & G. Stephenson, The Use and Significance of Pesticides in the Environment 63-72 (1979). These conditions can only be established through the kind of research and testing that, in this country, generates the data submitted pursuant to FIFRA. Id.

<sup>&</sup>lt;sup>42</sup> The Court's decisions involving the taking of intangible property have consistently recognized the special nature of such property. E.g., Armstrong v. United States, 364 U.S. 40, 44 (1960)(supplier's liens); Louisville Joint Stock Land Bank v. Radford, 295 U.S. 555, 596-97 (1935) (real estate liens); Lynch v. United States, 292 U.S. 571, 579 (1934)(contracts); United States v. [Footnote continued]

rights in that property. For the owners of trade secrets, the existence of their property is defined by their "right to exclude." The trade secret owner, of course, cannot prevent others from fairly and independently developing the same information, but the very essence of property in his trade secret is "the power to make use of it to the exclusion of the world." Hartley Pen Co. v. United States District Court, 287 F.2d 324, 328 (9th Cir. 1961) (quoting Cincinnati Bell Foundry Co. v. Dodds, 10 Ohio Dec. Reprint 154 (Super. Ct. 1887) (Taft, J.)). See Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470, 476 (1974); Painton & Co. v. Bourns, Inc., 442 F.2d 216, 223 (2d Cir. 1971); 1 R. Milgrim, Trade Secrets § 5.04[1] (1983). Quite simply, unless the owner of a trade secret maintains its confidentiality, he has no property. Kewanee Oil, 416 U.S. at 484.

Ignoring the nature of trade secret property, EPA once again invites the Court to weigh the interests of "the public" and those of Monsanto. EPA Brief at 33, 34-35, 38, 39. Monsanto has emphasized before that EPA's balancing test conflicts sharply with the Taking Clause. See pages 13-14 supra. The Taking Clause rejects EPA's notion that whether private property has been taken turns on how felicitous the purpose of the legislation happens to be. Whatever the outcome of EPA's "balancing test," the exercise is irrelevant to the taking of property in violation of the Fifth Amendment."

General Motors Corp., 323 U.S. 373, 378 (1945)(lease). Cf. United States Trust Co. v. New Jersey, 431 U.S. 1, 19 n.16 (1977) (contract rights constitute Fifth Amendment property).

<sup>&</sup>lt;sup>43</sup> Since the property involved differs greatly from case to case, as does the governmental action affecting the property, the Court has not formulated any single test for determining whether there has been a taking. See Penn Central Transp. Co. v. New York City, 438 U.S. 164, 175 (1978).

<sup>&</sup>lt;sup>44</sup> As Professor Michelman explained in *Property*, *Utility and Fairness:* Comments on the Ethical Foundations of "Just Compensation" Law, 80 Harv. L. Rev. 1165, 1193-94 (1967), the balancing test "cannot have anything to do with the" question whether a taking has occurred. See, e.g., *United States* v. General Motors Corp., 323 U.S. 373 (1945)(war department's taking of leasehold interest in manufacturing plant); *United States* v. Pewee Coal Co., 341 U.S. 114, 116 (1951)(wartime seizure of coal mine).

What is relevant here is the combined "practical effect" of the FIFRA amendments, Webb's Fabulous Pharmacies, Inc. v. Beckwith, 449 U.S. 155, 169 (1980), which order Monsanto to open its research files to anyone who wishes to remove the trade secrets contained therein and require Monsanto to deliver its hard-earned trade secrets to any rival firm that desires to use this Monsanto property to market competing products. Under Sections 10(b) and (d), and the last sentence of Section 3(c)(2)(A) as amended. EPA must make "available for disclosure to the public" within 30 days the registrant's trade secrets, including all of those relating to pesticide chemistry, metabolism and testing methodology. While EPA attempts to minimize the devastating consequences of these provisions by characterizing the recipients of Monsanto's trade secrets as "qualifying members of the public" or "certain classes of persons" (EPA Brief at 3, 37), the only private persons not so "qualified" are multinational and foreign pesticide firms. 45

Pursuant to these provisions, Monsanto's trade secret property would flow freely into the hands of any other company, "interest group," entity, or individual who desires it and from there into trade journals and other publications. Indeed, the amicus briefs filed in support of EPA highlight this fact. It is thus clear from the record that by both direct and indirect routes, Monsanto's business competitors can and would receive Monsanto's trade secrets, and the district court so found. J.S. App. at 21a-22a; Trial Exhs. 14, 47-51; Tr. 218, 250-51.

<sup>&</sup>lt;sup>45</sup> See note 10 supra. Section 10(g), by its terms, does not exclude domestic firms, foreign governments, foreign or multinational firms who do not produce or sell pesticides outside the United States, or other foreign non-business entities from the category of "qualified members of the public" (to borrow EPA's description) entitled to Monsanto's trade secrets. The provision specifically bars only firms "engaged in the production, sale or distribution of pesticides in countries other than the United States or in addition to the United States." 7 U.S.C. § 136h(g)(1982).

Monsanto, which is a multinational firm, is therefore not entitled to receive another company's trade secrets under Section 10(g). If Monsanto desires such property, it must pay for the trade secrets.

Having obtained Monsanto's trade secrets, such competitors would be able to destroy Monsanto's hard-earned innovative advantage by duplicating its technology, gaining leads for reconstructing its product formulas and for research into new compounds, developing new pesticides that Monsanto research had uncovered, and expanding uses for their competing products and registering their competitive pesticides abroad. See pages 24-25 supra.

With respect to the use provision. EPA's insistence that Monsanto's trade secret property is not taken conflicts with the very legislation EPA defends. Section 3(c)(1)(D) provides that when one company registers its pesticide by using research and test data owned by another, the owner is entitled to compensation. Congress had no authority to define "property" for purposes of the Fifth Amendment, PruneYard Shopping Center v. Robins, 447 U.S. 74, 84 (1980), and in enacting Section 3(c)(1)(D). Congress had no choice but to legislate in light of the "existing rules or understandings" that determine property interests. Board of Regents v. Roth, 409 U.S. 564. 577 (1972). See pages 15-19 supra. Consistent with these rules and understandings, Congress stated that companies like Monsanto retained "legal ownership" of their trade secrets after EPA received their data, that these companies had a continuing "proprietary interest" in their property and that the use provision eliminated the trade secret owner's "exclusive property."47 This is why Congress set up an arbitration scheme requiring "piggyback" registrants to pay the owner for using

<sup>&</sup>lt;sup>46</sup> The existence of the patent laws does not bear on whether trade secrets are taken under FIFRA. As the record demonstrates, patents on newly-discovered pesticide compounds are normally applied for early in the process and before much of the data submitted to support registration is developed. J.A. 159-61. The patent laws are irrelevant to the trade secrets at issue here; these unpatented trade secrets are not disclosed in the patent application. J.A. 165-68. See Johnson v. HEW, 462 F. Supp. 336 (D.D.C. 1978).

<sup>&</sup>lt;sup>47</sup> H.R. Rep. No. 1560, 95th Cong., 2d Sess. 29 (1978) (Conf. Report); S. Rep. No. 334, 95th Cong., 1st Sess. 31 (1977); H.R. Rep. No. 663, 95th Cong., 1st Sess. 41 (1977).

his property, and it is why Section 3(c)(1)(D)(ii) itself speaks of an owner's "right to compensation." Rather than supporting EPA, the legislative history of the FIFRA amendments simply confirms Congress' understanding that it was eliminating property rights, thereby destroying advantages gained by data owners through hard-earned innovation and an enormous commitment of resources. See Board of Trade v. Christie Grain & Stock Co., 198 U.S. 236, 250 (1905) (Holmes, J.).45

Among the few hard and fast rules set down under the Taking Clause, the Court has established one that is conclusive here: "the 'right to exclude,' so universally held to be a fundamental element of the property right, falls within this category of interests that the Government cannot take without compensation." Kaiser Aetna v. United States, 444 U.S. 164, 179-80 (1979); see also Loretto v. Teleprompter Manhattan

<sup>&</sup>lt;sup>48</sup> EPA extols the FIFRA amendments as a means to "reduce barriers to entry by allowing subsequent applicants to obtain registrations for products . . . without duplicating the data EPA already has in its possession." EPA Brief at 37. Even if this purpose made a difference under the Taking Clause, which it does not, the FIFRA amendments do not reduce barriers to entry. Instead, they create them.

A "barrier to entry" faces a company if its long-run costs of doing business are higher than the costs of another company in producing the same product. See, e.g., G. Stigler, The Organization of Industry 67-70 (1968); 2 P. Areeda & D. Turner, Antitrust Law ¶ 409a (1978); Demsetz, Barriers to Entry, 72 Am. Econ. Rev. 47 (1982). Because Monsanto now has to bear the costs (and run the risks) of creating trade secret research and test data while rival firms do not, the FIFRA amendments create a barrier to entry for firms like Monsanto. Prior to the 1978 changes in the law, all firms were treated equally.

EPA thus misuses the "barrier to entry" principle to refer to high start-up costs. As so used, it does nothing to advance EPA's constitutional arguments. No one, for example, would contend that because Monsanto has to build and operate a large and expensive plant in order to manufacture pesticides, Congress could force Monsanto to make pesticides for other, smaller companies in its plant. The Taking Clause would stand in the way of such regulation, as the Framers intended, just as it stands in the way of the FIFRA amendments at issue in this case.

CATV Corp., 458 U.S. 419, 435 (1982). For the owner of trade secret property, his right to exclude others, which the FIFRA amendments take away, is not merely "'one of the most essential sticks in the bundle of rights that are commonly characterized as property,' "it is the essential stick. Loretto, 458 U.S. at 433 (quoting Kaiser Aetna, 444 U.S. at 176). "If the trade secret owner cannot exclude others, if he must share his trade secrets with the world, he has no property. See page 32 supra; 1 R. Milgrim, Trade Secrets § 2.03 at 2-22 (1983); e.g., Drew Chemical Corp. v. Star Chemical Co., 258 F. Supp. 827, 834 (W.D. Mo. 1966). "

<sup>49</sup> PruneYard Shopping Center v. Robins, which EPA cites, lends no support to EPA. The Court there distinguished Kaiser Aetna on the basis that the federal government, unlike the states, had no authority to define "property" under the Taking Clause. 444 U.S. at 84. Moreover, in PruneYard, the state-created rights of speech of some private parties were set against the rights of another private party under the Fifth Amendment. The Court resolved this clash against the shopping center owners because they had "failed to demonstrate that the right to exclude others is so essential to the use or economic value of their property." Id. at 84. As the Court later explained in Loretto, the state-authorized limitation on the property owners in PruneYard was only temporary and therefore did "not absolutely dispossess the owner of his rights to use, and exclude others from, his property." 458 U.S. at 435 n.12. In this case, however, FIFRA authorizes the permanent destruction of Monsanto's right to exclude others from its trade secrets, which-unlike PruneYard-is indeed a right essential to the economic value of the property.

EPA argues that a manufacturer has no constitutional right to sell products without giving the consumer "fair" information about what is being sold. EPA Brief at 39. To the extent EPA is suggesting that the government has constitutional authority to regulate product labeling in order to prevent misbranding—which was the issue in Corn Products—EPA's argument is correct but irrelevant. On the other hand, if EPA means to suggest that the Fifth Amendment places no restraints on the government's taking of trade secrets, EPA's theory flies in the teeth of the cases discussed in the text. Such a theory would obviously read the Taking Clause out of the Constitution and render meaningless the Fifth Amendment principles that, as EPA itself acknowledges (EPA Brief at 33-34), govern whether a taking occurred.

Not only do the FIFRA amendments take Monsanto's trade secret property by eliminating its right to exclude, but also public disclosure of the trade secrets destroys the property root and branch. Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470, 484 (1974). This Court has consistently held that such a complete and irrevocable destruction of intangible property is a taking, E.g., Armstrong v. United States, 364 U.S. 40, 46 (1960)(materialman's lien); Louisville Joint Stock Land Bank v. Radford, 295 U.S. 555 (1935) (real estate liens); Pennsulvania Coal Co. v. Mahon, 260 U.S. 393 (1922)(mineral rights).51 The manner in which the FIFRA amendments destroy Monsanto's property—by transferring Monsanto's trade secrets to the public and Monsanto's competitors-flies in the face of this Court's holding in Webb's Fabulous Pharmacies, Inc. v. Beckwith, 449 U.S. 155, 164 (1980), that "a State, by ipse dixit, may not transform private property into public property without compensation." Neither may the federal government. To borrow Justice Brandeis' description in Thompson v. Consolidated Gas Utilities Corp., 300 U.S. 55, 79 (1937), the FIF-RA amendments present a "glaring instance of taking of one man's property and giving it to another."

Instead of addressing these points, EPA seeks to deflect attention away by focusing not on what has been taken, but on what supposedly remains after the FIFRA amendments. Although EPA concedes that Monsanto has been deprived of its right to exclude and acknowledges that a taking occurs when a regulation destroys all "property rights" (EPA Brief at 33, 35),

<sup>51</sup> Trade secret property rights are not just diminished, but obliterated, by public disclosure which is a conclusive "factor pointing toward government disclosures of trade secrets as takings." Connelly, Secrets and Smokescreens: A Legal and Economic Analysis of Government Disclosures of Business Data, 1981 Wis. L. Rev. 207, 251. See Harrington v. National Outdoor Advertising Co., 196 S.W.2d 786, 791 (Mo. 1946); see generally 1 R. Milgrim, Trade Secrets § 2.03 (1982) ("[t]he value, then, of a trade secret rests in the maintenance of secrecy"). See also Note, Constitutional Limitations on Government Disclosure of Private Trade Secret Information, 56 Ind. L.J. 347, 364-68 (1981).

it tries to soften FIFRA's impact by listing remaining interests that are in no sense incident to Monsanto's property rights in its trade secrets. EPA's argument that Monsanto "retains significant rights" in its data despite FIFRA (id. at 35) is wrong on several counts. The argument ignores the undeniable fact that Monsanto would retain none of its trade secret property embodied in this data. The argument fails as well because, in stating it, EPA is forced to use the adjective "significant" rather than "valuable" to describe Monsanto's supposed remaining rights. The destruction "of all value" in intangible property constitutes a taking, Armstrong v. United States, 364 U.S. at 48, and EPA surely knows as well as anyone that Monsanto's trade secrets become worthless when they are released to the world. Only a fool would pay Monsanto for something EPA gives away merely for the asking.

EPA, in short, does nothing but confound the subject when it asserts that Monsanto "retains the right" to exploit "the data" and to use it. EPA Brief at 35. Whatever rights Monsanto had in its trade secrets will become public rights as a result of FIFRA. Indeed, if there were any validity to EPA's novel "retained rights" theory, the Court would have decided Kaiser Aetna in favor of the United States because the owner there "retained significant rights" to sail on "his" pond and to swim and to fish in the pond even after the government opened it to the public. But what the government attempted to take from the owner of Kuapa Pond is precisely what FIFRA takes from Monsanto: the right to exclude others. Being forced to

<sup>&</sup>lt;sup>52</sup> Rather than retaining rights, Monsanto is exposed to potential liability as a result of the use provision. If a manufacturer who registered a pesticide by using Monsanto research and test data markets the product without adequate quality controls, an injured party might join Monsanto in a product liability suit. Such a careless manufacturer could conceivably even advertise its poorly-made product by proclaiming that it was backed by Monsanto research.

<sup>&</sup>lt;sup>53</sup> As a matter of trade secret law and common sense, Monsanto does not retain any trade secrets once they have been disclosed. See page 32 supra.

share one's property with others is, in Madison's words, being "obliged to relinquish" the property. As Kaiser Aetna firmly establishes, that constitutes a taking within the meaning of the Fifth Amendment no matter how reasonable the government's intentions may otherwise appear. \*\* See note 17 and pages 32-34 supra; United States v. Causby, 328 U.S. 256 (1946) (owner's retention of land after taking of easement does not avoid the taking).

Similarly, when EPA argues that Monsanto has been given the "valuable replacement right" of payment by competitors who use its property to register their pesticides (EPA Brief at 36), EPA at once confirms that Monsanto's property has been taken and that the Fifth Amendment has been violated. To the extent that its property is taken for a "public use," Monsanto is entitled to a "replacement right" but it is not the one FIFRA provides. Although the Fifth Amendment requires that "just compensation" be provided in such circumstances, FIFRA

<sup>54</sup> There is nothing to EPA's argument that the FIFRA amendments themselves deprive Monsanto of "investment-backed expectations" in its trade secret property. EPA Brief at 33-34. The argument is circular: EPA contends in effect that Monsanto's property has not been taken because, after FIFRA, Monsanto has no compensable property. There is no functional difference between EPA's argument in this regard and its contention, which is discussed above at pages 26-31, that Monsanto has no property because it consented to having its trade secrets used and disclosed. Only this bears adding. If Congress passes a statute taking private property for a public use. the owner may no longer have any expectations that he will continue to own the property. That, however, cannot render the statute constitutional if Congress fails to provide just compensation, as it has failed to do here. See Webb's Fabulous Pharmacies, 449 U.S. at 164. Every property owner is entitled to expect that the government will not take his property unless he is so compensated and that expectation is one legislation may not extinguish so long as the Fifth Amendment stands.

<sup>&</sup>lt;sup>55</sup> Moreover, the replacement value EPA ascribes to FIFRA's ten-year exclusive use period applies only for research and test data supporting the registration of pesticides containing a new active ingredient first registered after September 30, 1978. As discussed above, there are very few new active ingredients introduced, and Monsanto's latest product in this category was registered in 1975. See page 21 supra. The provision thus provides no replacement value to Monsanto. In addition, the amended disclosure provi-

provides nothing when Monsanto's property is destroyed through public disclosure, it provides nothing when others take advantage of Monsanto's trade secrets outside the registration process and, as EPA has now conceded (see pages 40-41 & note 56 infra), it provides less than "just compensation" when other private companies use Monsanto's property in order to market their competing products.

# III. "JUST COMPENSATION" IS NOT PROVIDED FOR THE TAKING OF MONSANTO'S TRADE SECRET PROPERTY.

The preceding discussion establishes that Monsanto's trade secrets are "private property" and that this Monsanto property is taken under FIFRA. Since EPA agrees that private arbitration under FIFRA does not satisfy the Fifth Amendment's mandate that "just compensation" be provided (see J.S. 23-24, 25; EPA Brief at 44, 46 n.32), all that remains is EPA's

sions compel revelation of the trade secrets relating to new "active ingredients" and impose no restrictions upon their use by competitors for purposes other than FIFRA registration. See pages 7-8 supra.

36 "Just compensation" for the taking of trade secrets must be the "full and perfect equivalent in money of the property taken." United States v. Miller, 317 U.S. 369, 373 (1943). As EPA points out, the arbitration scheme, rather than compensating Monsanto for the value of its trade secrets, only provides compensation for part of Monsanto's "costs of performing tests." EPA Brief at 44. Moreover, FIFRA provides no compensation in many instances when trade secrets are taken. See pages 7-8 supra. In addition, private arbitrators decide the compensation under FIFRA, yet determining "just compensation" is inherently a judicial inquiry, which not even Congress or the Executive Branch may assume. United States v. New River Collieries Co., 262 U.S. 341, 343-44 (1923); Monongahela Navigation Co. v. United States, 148 U.S. 312, 327 (1893). Finally, the scheme would violate the Constitution because the arbitration panel cannot even be considered an Article I tribunal. See note 11 supra. Compare Northern Pipeline Construction Co. v. Marathon Pipe Line Co., 458 U.S. 50 (1982), with Buckley v. Valeo, 424 U.S. 1 (1976).

In light of EPA's concession that the arbitration scheme was not meant to provide "just compensation," Monsanto agrees that there are no other constitutional issues regarding this aspect of FIFRA now properly before the Court and that such issues would not be ripe for adjudication in any event. EPA Brief at 44-45.

claim that Monsanto can recover "just compensation" under the Tucker Act (28 U.S.C. § 1491) by suing the United States in the Claims Court each time its trade secret property is disclosed or used pursuant to FIFRA. For the reasons that follow, the district court correctly rejected EPA's argument and properly enjoined the FIFRA amendments. J.S. App. 34a-36a.

Although EPA does not rely on FIFRA's arbitration scheme to show that "just compensation" is available (EPA Brief at 46 n.32), the scheme remains highly significant to the "just compensation" question. The provisions added to FIFRA in 1978 and their legislative history show not only that Congress designated arbitration as the exclusive means of recompensing trade secret owners for their property, but also that any judicial remedy outside the statute would conflict with FIFRA's design.

Under Section 3(c)(1)(D)(ii), competitors who use Monsanto's property must offer to pay Monsanto and to submit to binding arbitration. This offer to arbitrate is one that companies like Monsanto cannot refuse. If Monsanto or any other company that has supplied research data to EPA rejects the "piggyback" registrant's offer to arbitrate, FIFRA strips the owner of any right to be paid. Section 3(c)(1)(D)(ii) so provides in the clearest possible terms: any company refusing to arbitrate "shall forfeit the right to compensation for the use of the data in support of the application." 7 U.S.C. § 136(a)(c)(1)(D)(ii)(1982) (emphasis added).

In devising this private arbitration scheme, Congress had a number of objectives in mind. First, Congress concluded that the economic impact of destroying trade secrets through Section 10 public disclosure, which could stifle research and development, must be mitigated by requiring "piggyback" registrants to pay something for using the trade secret owner's data under Section 3. See S. Rep. No. 334, 95th Cong., 1st Sess. 41 (1977) (justifying the economic impact of disclosure on the basis that the data developer will be paid if another company uses the data to register a competing product). Second,

Congress wanted to put an end to what it and EPA viewed as intrusions by the courts in suits involving the status of trade secrets under FIFRA. See H.R. Rep. No. 343, 95th Cong., 1st Sess. 7-8 (1977); H.R. Rep. No. 663, 95th Cong., 1st Sess. 18 (1977). The House and Senate versions of the bill therefore provided that arbitration would be final, conclusive and not subject to further appeal in the courts. H.R. Rep. No. 1560, 95th Cong., 2d Sess. 31-32 (1978)(Conference Report). The provision was enacted in this form, with a slight modification to allow for judicial intervention solely in the event of fraud or misconduct by a party or an arbitrator. Third, Congress intended that the money to compensate data submitters come from the private sector, not the Treasury; data submitters were to receive whatever they could garner from their competitors in arbitration and nothing more. See S. Rep. No. 334, 95th Cong., 1st Sess. 17 (1977). After FIFRA's exclusive use and compensation periods expire, Section 3(c)(1)(D)(iii) thus provides "that there shall be no compensation at all" for the takings.57

To suggest, as EPA does, that despite these provisions trade secret owners may litigate their taking claims against the United States in the Claims Court is to contradict this legislation. It would be fundamentally inconsistent with Congress' design to subject trade secret owners to the penalty of forfeiting their "right to compensation" for refusing to arbitrate if they were entitled to be proceeding in the Claims Court in any event. Moreover, Congress hoped to avoid even arbitration proceedings by forcing the owner and the user to first negotiate over the amount to be paid. See FIFRA § 3(c)(1)(D)(ii). It is difficult to see how such negotiations could ever be fruitful when, regardless of the outcome, the owner could be fully compensated through the Claims Court, as EPA suggests. In addition, if EPA's argument were correct, there

<sup>&</sup>lt;sup>57</sup> Amchem Prods., Inc. v. Costle, 481 F. Supp. 195, 199 (S.D.N.Y. 1979), rev'd on other grounds sub nom. Union Carbide Agricultural Prods. Co. v. Costle, 632 F.2d 1014 (2d Cir. 1980), cert. denied, 450 U.S. 996 (1981).

is no reasonable explanation why Congress would ever have required "piggyback" registrants to pay a company for using its property. The research and test data would have been subject to public disclosure under Section 10 after the company first registered its product, long before any "piggyback" applications began reaching EPA, and by the time arbitration with the "piggyback" registrant took place, the data submitter could already have recovered on a judgment from the Claims Court awarding just compensation. Indeed, potential "piggyback" registrants would have every incentive to delay filing an application until the United States had fully compensated the owner for the loss of his trade secret property resulting from EPA's disclosing it. The only rational system in such circumstances would be for the "piggyback" registrant to idemnify the United States, but there is no such provision in FIFRA.

Still further, Congress would be shocked to learn that in passing amendments designed to prevent trade secret litigation under FIFRA, it had instead spawned an endless stream of such suits. Yet that is the gist of EPA's Tucker Act argument. According to EPA, each time a trade secret is taken under FIFRA, a cause of action for just compensation accrues in the Claims Court. EPA Brief at 43-44 n.31.

Citing Regional Rail Reorganization Act Cases, 419 U.S. 102 (1974), EPA contends that the proper inquiry is whether Congress withdrew the Tucker Act grant of jurisdiction to the Claims Court. EPA Brief at 41-42. That was the question in the Rail Cases but EPA ignores the reason why. With respect to the Rail Act, the Court decided that a Tucker Act remedy could co-exist with the statutory scheme, particularly since Congress had indicated a willingness to pay just compensation by appropriating tens of millions of dollars for this purpose. See 419 U.S. at 128-29, 133-34. In regard to FIFRA, however, suits in the Claims Court for takings of trade secret property would be inconsistent with the statutory scheme and Congress' purposes, as the legislative history reveals. For FIFRA, Congress appropriated not a cent to provide just compensation because all compensation was to come from the private benefi-

ciaries. If Congress had thought that FIFRA's use and disclosure provisions were to be implemented at public expense, it might have decided that the drain on the Treasury from FIFRA's taking of trade secrets would be too great. That, of course, is a judgment only Congress could make, despite the ostensible willingness of EPA to have the public shoulder such a huge financial burden. See EPA Brief at 44. But it is a judgment Congress did not make. Contrary to EPA's arguments, Congress decided that private arbitration was to be the exclusive means by which "just compensation," or indeed any compensation, would be provided to trade secret owners under FIFRA. 123 Cong. Rec. 25709 (1977) (Sen. Leahy).

Moreover, in contrast to the Rail Act, there is further evidence regarding FIFRA that Congress did not intend the Tucker Act to be available. One year after passage of the Rail Act of 1973, Congress enacted the Congressional Budget Act requiring, for the first time, the Congressional Budget Office to estimate what the five-year cost would be of any proposed legislation. 31 U.S.C. § 1353 (Supp. V 1981). These cost estimates must be included in each House and Senate committee report accompanying any public bill, thus enabling the members to vote on proposed legislation in light of how much it would drain the Treasury. The Congressional Budget Office's estimate accompanying both the Senate and House committee reports on the 1978 FIFRA amendments project no costs resulting from Tucker Act judgments against the United States. See H.R. Rep. No. 663, 95th Cong., 1st Sess. 71-73 (1977); S. Rep. No. 334, 95th Cong., 1st Sess. 116-17 (1977). Thus, when the members of the Senate and House voted on the 1978 FIFRA amendments, they did so on the basis that there would be no Claims Court judgments against the United States for FIFRA's takings of private property. In short, to accept

<sup>&</sup>lt;sup>38</sup> In contrast, when Congress passed the Rail Act in 1973, it was not required to project costs over the next five years, *Regional Rail Reorganization Act Cases*, 419 U.S. at 127-28, as the Congressional Budget Act of 1974 necessarily required Congress to do when it considered the 1978 FIF-RA amendments.

EPA's contention that the Tucker Act provides relief for FIF-RA's taking of trade secret property would be to conclude that the Members of both Houses of Congress had been deceived when they voted on this legislation in light of its projected costs.

The Tucker Act therefore is not available to cure FIFRA's failure to provide "just compensation" as the Fifth Amendment requires, and the district court properly enjoined EPA from implementing the statute's use and disclosure provisions.<sup>39</sup>

### IV. THE 1978 FIFRA AMENDMENTS TAKE MONSAN-TO'S TRADE SECRETS FOR A PRIVATE USE IN VIOLATION OF THE FIFTH AMENDMENT.

The Fifth Amendment also prohibits any taking by the government for a private use, regardless of whether compensation is paid. Thompson v. Consolidated Gas Utilities Corp., 300 U.S. 55, 80 (1937); Cole v. City of La Grange, 113 U.S. 1, 6 (1885). This proscription, reflecting the Framers' belief that property rights are the "essential nature of all free governments," exists as a fundamental limitation on the governmental transfer of property between private parties. Madisonville Traction Co. v. Saint Bernard Mining Co., 196 U.S. 239, 252 (1905). Recent federal and state court decisions reveal that, although applied sparingly, the Fifth Amendment's private use restriction is particularly applicable to legislation that unconditionally transfers property between private parties. \*\*

<sup>&</sup>lt;sup>59</sup> Even if a Tucker Act remedy were consistent with FIFRA, it would be inadequate to provide "just" compensation. Each use of Monsanto's trade secret data to register another's pesticide and each trade secret's disclosure would require Monsanto to bring suit after suit for money damages in the Claims Court, which is neither "certain" nor "reasonable" as the Fifth Amendment requires. See Dames & Moore v. Regan, 453 U.S. 654, 689 (1981).

<sup>\*\*</sup>O See, e.g., Midkiff v. Tom, 702 F.2d 788, 793 (9th Cir.), prob. juris. noted, 104 S. Ct. 334 (1983); Wells v. Air Prods. & Chems., Inc., 383 F. Supp. 146, 149 (N.D. W.Va. 1974); City of Owensboro v. McCormick, 581 S.W.2d 3, 5-6 (Ky. 1979); Phillips v. Foster, 211 S.E.2d 93, 96 (Va. 1975).

The district court correctly held that amended Section 3(c)(1)(D), by its own terms, takes Monsanto's property for a private use. Under this provision, Monsanto's trade secret property is used by private parties (Monsanto's competitors) for their own advantage, and Monsanto is deprived of its right to prevent such use and to prevent the competitors from receiving the resulting benefit. Indeed, EPA does not dispute that, 'out for the district court's injunction, Monsanto's property would be used for just such a purpose. J.A. 58-59. Recognizing that the true recipients of this governmental taking were private companies, Congress required them to pay their competitors directly for the taking in arbitration proceedings. See pages 7-8, 41-42 supra.

Such a governmental transfer between private parties contravenes the Fifth Amendment's private use limitation. In Thompson v. Consolidated Gas Utilities Corp., 300 U.S. 55 (1937), the Court overturned a comparable Texas Railway Commission order compelling private pipeline owners to transport, and afford a market for, the natural gas of independent wells instead of their own products. Justice Brandeis, speaking for a unanimous Court, held that this transfer to independent well operators "who have not contributed in money, services, negotiations, skill, forethought or otherwise to the development of such markets and the construction of such pipelines" constituted an impermissible taking of the pipeline owners' property for private use. Id. at 78. After scrutinizing the effect of the Commission's order, the Court rejected arguments that the regulation could be sustained as a means of preventing waste and protecting common gas reserves. Id. at 70. In Missouri Pacific R.R. v. Nebraska, 164 U.S. 403 (1896), the Court invalidated a state order permitting a private association to build a grain elevator on railroad property. Because the order did not ensure that use of the elevator would directly benefit the public, as opposed to the private recipients, the Court held that the order constituted an invalid transfer of the railroad's

property "to an association of private individuals . . . for their own benefit." Id. at 417.61

The FIFRA use provision violates the Fifth Amendment principles set forth in *Thompson* and *Missouri Pacific*. Monsanto is forced to share its property with its business rivals so that they can market competing products without doing the research and testing Monsanto had done. The private beneficiaries have sole discretion to decide whether to use Monsanto's property and are the ones who benefit at Monsanto's expense. So

The invalidity of this taking for private use is not avoided by EPA's recitation that Congress enacted the legislation to meet a public purpose under the Commerce Clause. Whether property taken by the government is for a public or private use is a judicial inquiry. Madisonville Traction Co. v. Saint Bernard

<sup>&</sup>lt;sup>61</sup> Accord, Chicago, Milwaukee & St. Paul R.R. v. Wisconsin, 238 U.S. 491, 499 (1915) (Wisconsin's transfer of railroad's property to individual passengers void because no showing of public benefit); Wells v. Air Prods. & Chems., Inc., 383 F. Supp. at 149-50 (transfer of private easement barred where there was no condition for public use).

The fact that Monsanto's trade secrets are in EPA's possession when competitors obtain use of the property does not make the use public. EPA is simply an instrument for the private use, and it is the private competitors who have sole discretion to initiate the taking, receive the right to use, and offer to pay for the private use.

<sup>&</sup>lt;sup>63</sup> Berman v. Parker, 348 U.S. 26 (1954), is not to the contrary. The case involved only land use reform, not governmental transfers of property between parties that compete against one another. The taking was carefully regulated in Berman to assure that the property would be used only in accordance with a comprehensive redevelopment plan. By contrast, FIFRA § 3(c)(1)(D) permits unfettered use by competitors, who may not share Monsanto's commitment to product safety and quality control. See note 52 supra.

<sup>&</sup>lt;sup>64</sup> EPA's contention that the FIFRA provisions serve a sufficient public purpose to be sustained as an exercise of Congress' power under the Commerce Clause, see EPA Brief at 19-26, does not pardon this violation of the Fifth Amendment. It has long been established that the Fifth Amendment is an independent limitation on Congress' substantive authority under the Commerce power. Kaiser Aetna v. United States, 444 U.S. 164, 174 (1979); United States v. Cress, 243 U.S. 316, 326 (1917). See also United States v. Security Industrial Bank, 103 S. Ct. 407, 410 (1982).

Mining Co., 196 U.S. at 252; Sears v. City of Akron, 246 U.S. 242, 251 (1918); Cincinnati v. Vester, 281 U.S. 439, 447 (1930). While Congress believed that the taking would increase competition in the pesticide industry, that is the beginning of the inquiry not the end, as Thompson shows, See Epstein, Not Deference, But Doctrine: The Eminent Domain Clause, 1982 Sup. Ct. Rev. 351, 365-69. In light of the direct private use involved here, such an indirect public benefit does not rise to the level required by the Fifth Amendment. "The legislature may act to increase competition by many means but simply taking property from A and giving it to B to create a new competitor is not one of them. Such a rationale would sustain any governmental taking merely on the basis that competition might be enhanced, a proposition this Court squarely rejected in Thompson. Cf. Cincinnati v. Vester, 281 U.S. at 447. See also Washington-Summers, Inc. v. City of Charleston, 430 F. Supp. 1013, 1015 (S.D. W. Va. 1977) ("property cannot be taken by eminent domain for a predominantly private purpose").67

<sup>&</sup>lt;sup>65</sup> See generally Note, Public Use, Private Use, and Judicial Review in Eminent Domain, 58 N.Y.U. L. Rev. 409 (1983); Note, Eminent Domain: Private Corporations and the Public Use Limitation, 11 U. Balt. L. Rev. 310 (1982); Meidinger, The "Public Use" of Eminent Domain, 11 Envtl. L. 1, 44-49 (1980). See also B. Ackerman, Private Property and the Constitution 190 n.5 (1977).

<sup>&</sup>lt;sup>66</sup> In recent decisions, state courts have recognized that the distinction between a public use permitting a taking and a general public interest is crucial to interpretation of the Taking Clause. Otherwise the private use limitation would be erased from the Constitution. See City of Owensboro v. McCormick, 581 S.W.2d 3, 6 (Ky. 1979) ("if public use was construed to mean that the public would be benefited . . . there would be absolutely no limit on the right to take private property'"); Baycol, Inc. v. Downtown Dev. Auth., 315 So.2d 451, 457 (Fla. 1975) (public benefit not synonymous with public use); Phillips v. Foster, 211 S.E.2d 93, 96 (Va. 1975) (same).

<sup>&</sup>lt;sup>67</sup> Several states have formulated this test in terms of a requirement that a taking cannot further predominantly private purposes. See Baycol, Inc. v. Downtown Dev. Auth., 315 So.2d 451, 455 (Fla. 1975); Pulos v. James, 302 N.E.2d 768, 771 (Ind. 1973); Burger v. City of Beatrice, 147 N.W.2d 784, 791 (Neb. 1967); Hogue v. Port of Seattle, 341 P.2d 171, 192 (Wash. 1959); Opinion of the Justices, 126 N.E.2d 795, 803 (Mass. 1955).

#### CONCLUSION

For the foregoing reasons, the judgment of the district court should be affirmed.

Respectfully submitted,

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IN THE

# Supreme Court of the United States

OCTOBER TERM, 1983

WILLIAM D. RUCKELSHAUS, ADMINISTRATOR, UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, Appellant

V.

#### MONSANTO COMPANY

On Appeal From The United States District Court For The Eastern District Of Missouri

### SUPPLEMENTAL BRIEF OF APPELLEE MONSANTO COMPANY

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### IN THE

# Supreme Court of the United States

OCTOBER TERM, 1983

No. 83-196

WILLIAM D. RUCKELSHAUS, ADMINISTRATOR, UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, Appellant

V.

MONSANTO COMPANY

On Appeal From The United States District Court For The Eastern District Of Missouri

### SUPPLEMENTAL BRIEF OF APPELLEE MONSANTO COMPANY

Monsanto Company submits this Supplemental Brief pursuant to Rule 35.5 of the Rules of this Court in order to correct a misimpression that may have been created by EPA's citation of new authorities in its Reply Brief.

For the first time in its Reply Brief (at 2 n.1), EPA quotes and relies upon certain Food and Drug Administration regulations (21 C.F.R. §§ 71.15, 171.1(h)). The Court may be led to believe that under these regulations, all of the data a company submits — including trade secrets — in support of premarketing approval of food additives and color additives become available for public disclosure. EPA fails to point out, however, that the regulations it relies upon expressly exempt "trade sec-

rets" from public disclosure. See 21 C.F.R. §§ 71.15(a)(2), (a)(4), (a)(5), (b)(1)-(3), 171.1(h)(1)(ii), (iv), (v), (2)(i)-(iii). The Food and Drug Administration's regulations define "trade secrets" to include "any formula, pattern, device" used in a company's business, which gives the company "an opportunity to obtain an advantage over competitors who do not know or use it." 21 C.F.R. § 20.61(a). See also Monsanto's Brief, at 16.

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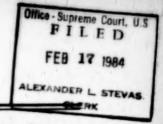
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# In the Supreme Court of the United States

OCTOBER TERM, 1983

WILLIAM D. RUCKELSHAUS, ADMINISTRATOR
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY,
APPELLANT

ν.

MONSANTO COMPANY

ON APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF MISSOURI

REPLY BRIEF FOR THE APPELLANT

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### TABLE OF AUTHORITIES

												1	Pa	g	e
Cases:															
Andrus v. Allard, 4	44	ı	J.	S.	51								3	, '	4
Statutes and regulations:															
21 U.S.C. 348(a)(2)															2
21 U.S.C. 376(a)(1)							4							4	2
21 C.F.R. (1983):															
Section 71.15			٠												2
Section 171.1(h)	)														2

# In the Supreme Court of the United States

OCTOBER TERM, 1983

No. 83-196

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MONSANTO COMPANY

ON APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF MISSOURI

#### REPLY BRIEF FOR THE APPELLANT

Appellee's generalizations about the commercial importance of trade secrets and the extensiveness of its research activities are not responsive to the particular uses made of testing data in the FIFRA registration scheme or to the limited nature of FIFRA's public disclosure requirement. Similarly overdrawn are appellee's analogies to cases involving physical invasion of real or other tangible property or the expropriation of liens, contract rights or other intangibles representing discrete entrepreneurial transactions. The health and safety information at issue here is not developed for marketing as a separate commercial product, but instead is a component part of an effort designed to culminate in the development and marketing of a pesticide. Appellee's ability to manufacture and market that product is fully preserved under FIFRA. Accordingly, appellee has

not been deprived of the primary means of commercially exploiting its endeavors. To the extent the provisions at issue impede the possibility of appellee's developing a secondary market for the data themselves, such a market would largely be a creation of FIFRA's own registration requirements and is, in any event, properly subject to diminution resulting from Congress's regulatory efforts to enhance health and safety protections in the marketing and use of pesticides.

1. Appellee points out (Br. 31) that if FIFRA were repealed altogether and registration of pesticides were no longer required, "[r]esearch and testing at Monsanto would necessarily proceed \* \* \*." In that event, however, any competitor would be free to market copies of Monsanto's unpatented end-products, without any necessity of duplicating Monsanto's testing or gaining access to its testing data. And, hypothetically, instead of enacting FIFRA, Congress could have required registration, supported by testing data, only of new pesticide products, which (if unpatented) could then freely be copied by other manufacturers.

These hypotheticals amply show that, in the absence of FIFRA, Monsanto would have no protection (other than that afforded by the patent laws) against competition in the manufacture of its pesticides.<sup>2</sup> The fact that Congress, in

¹This is the method of accommodating interests in public health, innovation, and competition in the Food and Drug Administration's approval systems for food additives and color additives. These call for premarketing submissions only by the pioneer company; competitors need obtain no approvals before marketing copies of an approved product (21 U.S.C. 348(a)(2); 21 U.S.C. 376(a)(1)). And, "[a]ll safety and functionality data and information submitted" by the pioneer company are "available for public disclosure" (21 C.F.R. 71.15, 171.1(h)).

<sup>&</sup>lt;sup>2</sup>Trade secret protection of its formulas and manufacturing processes, of course, remains unaffected by FIFRA.

FIFRA, afforded only limited non-patent protection to innovators, by providing them with certain rights to periods of exclusive use and to compensation from competitors for part of the cost of testing, is thus not a diminution, but instead is an enhancement, of the rights against competition that would exist for the innovator in the absence of the statute. This fundamental inconsistency with appellee's "taking" claim should not be allowed to be obscured by reliance on form over substance—i.e., by the mere fact that FIFRA provides this enhanced protection against competition in the form of conditioning the issuance of registrations to competitors based on the innovator's previously submitted testing data. That appellee would prefer the additional (economically inefficient) obstacle of requiring competitors to duplicate the testing does not mean that its property has been taken.

2. FIFRA's provision for disclosure to the consuming public of health and safety data is a narrowly drawn condition on the right to market these potentially dangerous chemical products that is reasonably related to protection of the public health and safety. In Andrus v. Allard, 444 U.S. 51 (1979), the Court held that the Eagle Protection Act's total prohibition, because of environmental concerns, of the marketing of eagle feathers was not a "taking" requiring compensation. The Court pointed out that appellees retained the right to possess, transport, donate, devise, or exhibit their property, but it recognized that the prohibition (applied by regulation to pre-Act as well as post-Act property) "prevent[s] the most profitable use of appellees' property" (444 U.S. at 66). Here, Congress, in an area of even more comprehensive environmental danger and concern, has preserved the most profitable use of appellee's total endeavor—the manufacture and marketing of the pesticide end-product. In return, in order to enhance protection of the public health and safety from the dangers posed by the

marketing and use of these chemicals, Congress has required a limited disclosure to the consuming public of pertinent health and safety data.<sup>3</sup> The mere fact that appellee can separately label as a "trade secret" its interest in retaining such information should not lead to a different result from Allard, which, unlike this case, involved destruction of the most valuable strand of the "bundle" of property rights (444 U.S. at 66).

For these reasons and the reasons stated in our opening brief,4 the judgment of the district court should be reversed.

Respectfully submitted.

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FEBRUARY 1984

<sup>&</sup>lt;sup>3</sup>Although Monsanto (Br. 5-6) points to alleged EPA mistakes in administering the statute, the record shows that EPA has strived to adhere carefully to the statutory limitations on disclosure. J.A. 208, 248-250, 251.

<sup>&</sup>lt;sup>4</sup>We note that Monsanto expressly agrees (Br. 40 n.56) with our contention that the district court erred in holding the constitutionality of the arbitration and compensation scheme ripe for review. See pages 44-47 of our opening brief.

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# Supreme Court of the United States CLERK

OCTOBER TERM, 1983

WILLIAM D. RUCKELSHAUS, ADMINISTRATOR, United States Environmental Protection Agency. Appellant,

MONSANTO COMPANY,

Appellee.

On Appeal From The United States District Court For The Eastern District Of Missouri

BRIEF AMICUS CURIAE on behalf of ABBOTT LABORATORIES, AMERICAN CYANAMID COMPANY, AMERICAN HOECHST CORPORATION, BASE WYANDOTTE CORPORATION, CHEVRON CHEMICAL COMPANY, CIBA-GEIGY CORPORATION, DOW CHEMICAL U.S.A., E.I. DU PONT DE NEMOURS & CO., ELANCO PRODUCTS COMPANY, ICI AMERICAS INC., MOBAY CHEMICAL CORPORATION, RHONE-POULENC, INC., ROHM AND HAAS COMPANY, UNION CARBIDE AGRICULTURAL PRODUCTS COMPANY, INC., UNIROYAL, INC. AND ZOECON CORPORATION

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# TABLE OF CONTENTS

	Page
INTEREST OF THE AMICI CURIAE	
STATEMENT OF THE CASE	2
(i) The Importance Of Research To The Pesticide Industry	2
(ii) The Value Of Research Data	
(iii) The Effect Of The FIFRA "Use" And "Dis-	
closure" Provisions	
SUMMARY OF ARGUMENT	9
Argument	11
I. TRADE SECRET RESEARCH DATA ARE PROPERTY PRO TECTED BY THE FIFTH AMENDMENT	11
II. TRADE SECRET RESEARCH DATA ARE "TAKEN" WITH IN THE MEANING OF THE FIFTH AMENDMENT BY THE PROVISIONS OF FIFRA	2
A. The FIFRA Provisions Completely Destroy The Value Of The Trade Secret Data	1
B. Because The FIFRA Provisions Expropriate Private Property, They Constitute A Taking	17
III. THE TAKING EFFECTED BY FIFRA IS UNCONSTITUTIONAL AND WAS PROPERLY ENJOINED	21
A. The Taking Of The Trade Secret Research Data Is For A Private Use	21
B. The Taking Is Without Just Compensation	22
C. Application Of The Tucker Act To Provide Just Compensation In This Case Would Violate Article I, Section 9, Clause 7 Of The Constitu- tion	
D. The Claims Court Does Not Have Con-	
stitutional Power To Adjudicate Taking Claims, And There Is No Appropriate Forum For Data Originators To Invoke A Tucker Act	
Remedy	28
Conclusion	30

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CASES: P	age
Addison v. Huron Stevedoring Corp., 204 F.2d 88 (2d Cir.), cert. denied, 346 U.S. 877 (1953)	14
Andrus v. Allard, 444 U.S. 51 (1979)	20
Cincinnati v. Vester, 281 U.S. 439 (1930)	21
Crowell v. Benson, 285 U.S. 22 (1932) 29	, 30
Duke Power Co. v. Carolina Environmental Study Group, Inc., 438 U.S. 59 (1978)	, 27
E.I. du Pont de Nemours & Co. v. United States, 288 F.2d 904 (Ct. Cl. 1961)	16
Frost & Frost Trucking Co. v. Railroad Commission, 271 U.S. 583 (1926)	, 15
Garrity v. New Jersey, 385 U.S. 493 (1967)	13
Glidden Co. v. Zdanok, 370 U.S. 530 (1962)	28
Hamilton v. Kentucky Distilleries & Warehouse Co., 251 U.S. 146 (1919)	20
Hart's Case, 16 Ct. Cl. 459 (1880), aff'd sub nom. Hart v. United States, 118 U.S. 62 (1886)	24
Hooe v. United States, 218 U.S. 322 (1910)	24
Hurley v. Kincaid, 285 U.S. 95 (1932)	26
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(1979) 14, 16	, 18
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Loan Association v. Topeka, 87 U.S. (20 Wall.) 655 (1874)	22
Loretto v. Teleprompter Manhattan CATV Corp., 458 U.S. 419 (1982)	, 19
Louisville Joint Stock Land Bank v. Radford, 295 U.S. 555 (1935)	, 28
Lynch v. United States, 292 U.S. 571 (1934)	27
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Northern Pipeline Construction Co. v. Marathon Pipe Line Co., 458 U.S. 50 (1982) 28, 29,	30
Pacemaker Diagnostic Clinic, Inc. v. Instromedix, Inc., 712 F.2d 1305 (9th Cir. 1983), reh'g granted, Nos. 82-3152, 82-3182 (9th Cir. Oct. 20, 1983)	29
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Pennsylvania Coal Co. v. Mahon, 260 U.S. 393 (1922)	14
Perry v. United States, 294 U.S. 330 (1935)	27
Reeside v. Walker, 52 U.S. (11 How.) 272 (1850)	24
Regional Rail Reorganization Act Cases, 419 U.S. 102 (1974) pass	im
Ruckelshaus v. Monsanto Co., 104 S. Ct. 3 (1983)	16
Standard Airlines, Inc. v. Civil Aeronautics Board, 177 F.2d 18 (D.C. Cir. 1949)	12
Sutton v. United States, 256 U.S. 575 (1921)	24
Thompson v. Consolidated Gas Utilities Corp., 300 U.S. 55 (1937)	21
Thorpe v. Housing Authority of Durham, 386 U.S. 670 (1967)	13
Union Carbide Agricultural Products Co. v. Ruckel- shaus, 571 F. Supp. 117 (S.D.N.Y. 1983)	23
United States v. Causby, 328 U.S. 256 (1946)	26
United States v. Cress, 243 U.S. 316 (1917) 20,	22
United States v. Doullut, 213 F. 729 (5th Cir. 1914)	24
United States v. General Motors Corp., 323 U.S. 373 (1945)	11
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Yearsley v. W.A. Ross Construction Co., 309 U.S. 18 (1940)	26

# **Table of Authorities Continued**

Pa	ge
CONSTITUTION, STATUTES AND REGULATIONS:	
U.S. Const. art. I, § 9, cl. 7 passi	im
U.S. Const. art. III pass	im
U.S. Const. amend. V passet	im
Anti-Deficiency Act, 31 U.S.C. § 665 (1976 & Supp. V	26
	28
Federal Courts Improvement Act of 1982, Pub. L. No. 97-164, 96 Stat. 25	28
Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. §§ 136-136y (1982)	im
Tucker Act, ch. 359, 24 Stat. 505 (1887) passet	im
28 U.S.C.A. §§ 171(a), 172(a) (West Supp. 1983)	28
28 U.S.C.A. § 2517(c) (West Supp. 1983)	24
31 U.S.C. § 724a (1976)	25
7 C.F.R. § 1.3(b)(1) (1949)	7
7 C.F.R. § 1.4(b)(15) (1972)	7
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	Page
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U.S. Dep't of Agriculture, Agricultural Outlook (Nov. 1983)	3

### IN THE

# Supreme Court of the United States

OCTOBER TERM, 1983

No. 83-196

WILLIAM D. RUCKELSHAUS, ADMINISTRATOR,
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY,
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V.

MONSANTO COMPANY,

Appellee.

On Appeal From The United States District Court For The Eastern District Of Missouri

BRIEF AMICUS CURIAE

on behalf of

ABBOTT LABORATORIES, AMERICAN
CYANAMID COMPANY, AMERICAN HOECHST
CORPORATION, BASF WYANDOTTE
CORPORATION, CHEVRON CHEMICAL
COMPANY, CIBA-GEIGY CORPORATION,
DOW CHEMICAL U.S.A., E.I. DU PONT DE
NEMOURS & CO., ELANCO PRODUCTS
COMPANY, ICI AMERICAS INC., MOBAY
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RHONE-POULENC, INC., ROHM AND HAAS
COMPANY, UNION CARBIDE
AGRICULTURAL PRODUCTS COMPANY, INC.,
UNIROYAL, INC. AND ZOECON
CORPORATION

#### INTEREST OF THE AMICI CURIAE

This brief amicus curiae is filed on behalf of sixteen companies engaged in the discovery, research, development, testing and sale of pesticide chemicals. The amici and other manufacturers have spent billions of dollars on pesticide research and development. The product of their R&D is reflected in proprietary and trade secret research data, many of which are submitted to the U.S. Environmental Protection Agency to support the registration of pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), 7 U.S.C. §§ 136-136y (1982). The amici have a vital interest in preventing their research data from being appropriated by the Government for the private use of their competitors in contravention of the Fifth Amendment to the Constitution.

The amici urge affirmance of the district court's holding that the challenged provisions of FIFRA, which authorize the unconsented use and disclosure of privately owned trade secret research data by the Government for the benefit of competitors, work an unconstitutional taking of property for private use without just compensation.<sup>2</sup>

#### STATEMENT OF THE CASE

#### (i) The Importance Of Research To The Pesticide Industry

The pesticide industry is a vital component of the agricultural economy.<sup>3</sup> Due in large part to effective pesticides, Amer-

<sup>&</sup>lt;sup>1</sup> In 1982, manufacturers reported spending \$527 million on pesticide research and development. 1982 Industry Profile Survey of the National Agricultural Chemicals Association ("NACA Survey") at 7. Since 1971, industry R&D expenditures have exceeded \$3 billion. See 1971-1982 NACA Surveys.

<sup>&</sup>lt;sup>2</sup> The amici have obtained written consent from both parties to file this brief.

<sup>&</sup>lt;sup>3</sup> Economic Research Service, U.S. Dep't of Agriculture, Implications of Pesticide Regulations, Rpt. No. AGESS810730, at 2-4, 11-23 (1981).

ican farmers feed the nation and supply one fourth of the food needs of the world.4

The lifeblood of the pesticide industry is research and development. The several dozen principal manufacturers of pesticides support extensive research programs. Painstaking R&D is necessary to discover or synthesize the very few chemicals that possess the unique characteristics required of a successful pesticide: the ability to selectively control an unwanted target pest without adversely affecting humans and other living organisms in the environment. Because hundreds of thousands of compounds have been screened over the past years for pesticidal potential,6 and the "easy" ones already have been found, the development of a new pesticide today is an arduous undertaking. The difficulty of discovering a chemical that has these rare characteristics, that is economical to produce and use, and that meets society's demands for environmentally and toxicologically safe products, makes pesticide research increasingly risky, time-consuming and expensive.7

<sup>&</sup>lt;sup>4</sup> U.S. pesticide sales in 1982 were \$4.2 billion. Herbicides, used principally to control weeds in food crops, accounted for nearly 70 percent of this market, and insecticides 21 percent. See 1982 NACA Survey at 4. Herbicides used on the \$20 + billion corn crop, for example, have been shown to increase crop yields by 25 percent. Hawkins, Economic Analysis of Herbicide Use in Various Crop Sequences, 17 Ill. Agric. Econ. No. 1, at 8-13 (1977); U.S. Dep't of Agriculture, Agricultural Outlook 41 (Oct. 1983). Pesticides in general contribute billions of dollars to the country's \$140 + billion agricultural production. U.S. Dep't. of Agriculture, Agricultural Outlook 12 (Nov. 1983).

<sup>5 1982</sup> NACA Survey at 2.

<sup>&</sup>lt;sup>6</sup> Between 1974 and 1982, more than 600,000 compounds were screened by companies responding to industry surveys. See 1974-1982 NACA Surveys.

<sup>&</sup>lt;sup>7</sup> EPA's Office of Pesticide Programs characterized the pesticide industry as having

large R&D investments as a percent of sales revenue; significant risk in product development, with large expenditures on unsuc-

In 1982, 120,000 chemicals were tested for pesticidal activity, yet only thirteen new products were registered by EPA. Of those pesticides registered, only a fraction will achieve sufficient commercial success to recoup their R&D costs before the patent expires. To produce this handful of "winners," the industry spent over one-half billion dollars on R&D in 1982, employing nearly 6,000 research scientists and technicians. For the new products registered in 1982, it took an average of nine years after discovery to complete R&D and obtain the first full EPA registration (six years for conditional registration), In ullifying a major part of the patent life. The cost of this research program exceeded \$40 million for each new chemical registered.

#### (ii) The Value Of Research Data

Proprietary and trade secret research data are an intrinsic part of industry's extensive pesticide R&D effort. They con-

cessful as well as successful products; extensive product screening and testing programs; considerable time lag from invention to commercialization of product; and competition among proprietary products of different companies.

Office of Pesticide Programs, Environmental Protection Agency, Evaluation of the Possible Impact of Pesticide Legislation on Research and Development Activities of Pesticide Manufacturers at 2 (Feb. 1975).

<sup>\* 1982</sup> NACA Survey at 7.

<sup>&</sup>lt;sup>9</sup> See generally Goring, The Costs of Commercializing Pesticides, Pesticide Management and Insecticide Resistance 31-32 (1977); Gilbert, The Increasing Riskiness of the Pesticide Business, Farm Chemicals (Apr. 1978).

<sup>10 1982</sup> NACA Survey at 7, 19.

<sup>11</sup> Id. at 7.

<sup>&</sup>lt;sup>12</sup> Id. See also Council for Agricultural Science and Technology, Impact of Government Regulation on the Development of Chemical Pesticides for Agriculture and Forestry, Rpt. No. 87 at 8, Table 4 (1981).

tain elaborate procedures and results of each manufacturer's voluminous research, and represent the collective corporate body of knowledge concerning each product. Without this essential information, the chemical has no value. These data enable the manufacturer to determine the conditions necessary for the effective and safe use of the chemical. Because they prove safety and effectiveness, the data are the key to the market. The immediate and primary use of the research data is to support federal, state, and international marketing approvals. But beyond their utility for registration purposes, the data are the essential building blocks for future innovations, and provide insights that are valuable for the development of improved or related products. The data also contain innovative and state-of-the-art scientific techniques developed during the research process.

Consequently, the research data are the essence of any pesticide and have enormous value. <sup>13</sup> They are a critical element of interfirm competition.

The value of these research data—and the inadequacy of the existing pesticide law to protect them—has been recognized by the same congressional committees that drafted the 1978 FIFRA amendments now under challenge. In its 1982 report approving legislation to remedy the problems with the 1978 FIFRA amendments, the House Committee on Agriculture stated:

If a company's safety, health and environmental fate data on a given pesticide were obtained by another

<sup>&</sup>lt;sup>13</sup> Because so few of the pesticides tested become successful commercial products, the value of the research data for a "winner" typically exceeds by many times the direct cost of testing that one product. The value reflects not only the cost of the massive research program necessary to produce the winner, and the risks involved in the development and regulatory approval process, but also the commercial advantage of owning data to support the marketing of a proven safe and effective product. For a research intensive company, the occasional winner must pay for all of the many losers.

competing firm, the competing firm would gain a number of advantages from the opportunity to study this information. First, the company would gain a detailed appreciation of the toxicity and environmental properties of the compound. This knowledge, in turn, is useful in many ways. The toxicity of a compound is a key factor in establishing the regulatory status of the pesticide, and how extensive a list of crop uses the Agency might ultimately be able to approve for the pesticide.

A compound's toxicity and environmental properties also are suggestive of the properties that similar compounds are likely to exhibit. If a compound displays particularly attractive and perhaps unanticipated properties, the competing firm might well choose to engage or significantly expand product synthesis work within the same or closely associated families of chemistry.

In addition, a chance to review another company's safety and health data on a pesticide may readily yield scientific leads of significant value to a competitor. The ability to gain detailed knowledge of the chemical and analytic methods utilized in particular studies may be extremely useful to competitors especially if the studies lay out analytic methods readily applicable to conducting comparable research needed to ascertain the safety, efficacy, mode of action, or environmental fate of other compounds. Many pesticide manufacturers have developed such methodologies, creating substantial qualitative improvements in the ability of scientists to understand and monitor the activity and environmental fate of the pesticide in the environment. These innovations greatly benefit both the innovating company and the EPA in that a more precise and reliable scientific assessment of a pesticide's safety can be carried out through their application.

The value of these innovative chemical and analytic methodologies to competitors can be substantial since the same methods may be easily and quickly adapted and applied to other pesticides which competing firms may already have under development. The investment and time period needed to obtain subsequent pesticide

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registrations may be shortened considerably, perhaps by a number of years.

H.R. Bep. No. 566, 97th Cong., 2d Sess. 42-43 (1982) (emphasis added). 14

Additionally, the Senate Committee on Agriculture, Nutrition, and Forestry stated:

Another type of economic harm from uncontrolled data disclosure that could be experienced by individual pesticide manufacturers, or by the industry as a whole, results from the use of disclosed data to gain pesticide registrations in other nations. Foreign pesticide markets are growing more rapidly than the domestic market. The profit potential for a firm investing in the development of a given pesticide, especially a new compound for which tens of millions of dollars have already been invested in research and development work, is becoming increasingly dependent on successful penetration into global markets.

S. Rep. No. 551, 97th Cong., 2d Sess. 21 (1982) (emphasis added).

Because pesticide research data have such a high commercial value, historically they have been considered proprietary and trade secret information, and maintained in confidence, both by the manufacturers and by the government officials to whom they have been entrusted. See, e.g., Monsanto Co. v. Acting Administrator, EPA, J.S. App. 26a. 15

<sup>&</sup>lt;sup>14</sup> H.R. 5203 was passed by the House of Representatives on August 11, 1982. A similar bill was reported by the Senate Committee on Agriculture, Nutrition, and Forestry on September 20, 1982, but did not reach the Senate floor for a vote before the expiration of the Ninety-seventh Congress.

<sup>&</sup>lt;sup>15</sup> See also 7 C.F.R. § 1.3(b)(1) (1949) (providing that reports and supporting data submitted to USDA by applicants are administratively confidential); 7 C.F.R. § 1.4(b)(15) (1972) (providing that "data concerning products and formulations provided by industry for research purposes or in connection with the Department's registration and other regulatory functions" are administratively confidential); 7 C.F.R. § 370.13(d) (1968) (providing that "scientific and technical"

# (iii) The Effect Of The FIFRA "Use" and "Disclosure" Provisions

The "use" and "disclosure" provisions of the 1978 FIFRA 16 effect a government-compelled transfer of the property of an owner of research data to other private persons. The use provision forces the data owner to give to his competitors one of the most important and valuable uses of his property: the use of the data to obtain a U.S. pesticide registration. The disclosure provision compels the owner to grant the use of his data to the world at large, destroying their trade secrecy. In combination, the use and disclosure provisions force the owner to give all commercial uses of his proprietary data to competing concerns.

The effect of this statute is to transfer the value of the right to use the data from their owner to others. The statute both bestows immediate wealth upon competitors who contributed nothing to the creation of the data, and simultaneously renders them virtually worthless to the owner who did expend the labor, skill and money needed to produce them.

The data owner is entirely dependent on a few "winners" to repay the enormous R&D expenses for testing the thousands of chemicals necessary to achieve one success. As long as the owner maintains exclusive control over the right to use his data, he can attempt to price a successful product so that he can recover his R&D investments. But when imitators who con-

data on products" and "data in research studies" where disclosure would adversely affect the respondent are trade secrets and confidential); 32 Fed. Reg. 9318-19 (1967) (amending 10 C.F.R. § 5.74 and Appendix A(11) to provide that "data in support of petitions relating to pesticide chemicals" are trade secrets and confidential).

<sup>&</sup>lt;sup>16</sup> The "use" provision, section 3(c)(1)(D), authorizes EPA to consider and rely upon the originator's research data to support registrations for subsequent applicants for similar products. The "disclosure" provision, section 10(d) (coupled with section 3(c)(2)(A)), requires EPA to make research data "available for disclosure to the public."

tributed nothing to this research effort are permitted to use the data to register imitation products in competition with the owner, they can price their imitation products at levels that do not reflect the need to recoup any R&D expense. As a result, the risk that the owner can no longer recover his investment is greatly increased and his research data may no longer have any competitive value to him. As is the case whenever trade secret property is disclosed to and used by competitors of the owner, the loss of exclusivity of use destroys the proprietary value of the property to its creator.

The FIFRA use and disclosure provisions will have a chilling effect on innovation. By diminishing the prospect that a pioneering company will recover its research investment, the FIFRA provisions will discourage R&D. Firms will be reluctant to make the extraordinary commitments required for pesticide research if they know that an imitator will be able to reap the fruits of their labors.

#### SUMMARY OF ARGUMENT

Through their labors and investments in research and development, Monsanto and the *amici* have created valuable trade secret research data which are property interests within the ambit of the Fifth Amendment. By transferring the right to use and enjoy such trade secret data from their owners to competitors, and by mandating their publication, the 1978 FIFRA destroys the value of the data to the owners and transfers their value to other private parties. The statute has all the characteristics of laws that this Court has consistently held to be takings cognizable under the Fifth Amendment.

The Government seeks to avoid the consequences of the Fifth Amendment by arguing that data owners may constitutionally be required to surrender their Fifth Amendment rights in order to obtain pesticide registrations. It is settled, however, that the strictures of the Fifth Amendment may not be evaded in this manner: The Government cannot require persons to surrender their Fifth Amendment rights as a condition for obtaining a license to do business. If such requirements

were permissible, the Fifth Amendment would be meaningless, for the Government could compel citizens to surrender property rights in return for the privilege of receiving a social security card, driving on interstate highways, or engaging in any commercial activity within the penumbra of federal regulatory power. The Government could not directly expropriate data owners' property rights without paying just compensation; and what it cannot do directly, it cannot do indirectly by imposing a "condition on a privilege."

The Government also contends that the FIFRA provisions should be affirmed as "regulations" of data owners' rights, based upon a "balancing" of the harm to owners against perceived benefits to the public. The Government's argument is both unavailing and misplaced. It is unavailing because even when evaluated under the standards for regulations that impose use restrictions, FIFRA unquestionably works a taking of data owners' trade secret property.

It is misplaced because this is not, in fact, a case of regulation. FIFRA does not purport to regulate the owners' use of their trade secret property to prevent the infliction of a perceived harm to the public interest, or to promote the public welfare. To the contrary, here the Government is simply appropriating the right to use the owner's property in order to bestow that right upon other individuals for their commercial benefit. Such "appropriation" is the textbook example of a taking. Even if, as EPA contends, public policy favors the acquisition of these property rights, and the acquisition is otherwise within Congress' power, the Fifth Amendment requires that Congress proceed by way of eminent domain.

Finally, the taking effected by the FIFRA provisions violates the Fifth Amendment because it is an illegal "private taking" and because data owners are not provided just compensation. Because the taking is for the benefit of individual competitors, it is a "private taking" and illegal per se regardless of just compensation. But, in addition, data owners are precluded from recovering just compensation for the taking of their property. The language of FIFRA demonstrates that

Congress has withdrawn the Tucker Act as a means for owners to seek just compensation. The Tucker Act also is not available here because Congress has not appropriated funds for the taking and has indicated an intent that no federal monies be obligated for this purpose. Even if the Tucker Act were available, however, the Claims Court could not adjudicate taking claims because it is not an Article III court. Just compensation thus is not available to data owners for the taking of their property by FIFRA.

#### ARGUMENT

#### I. TRADE SECRET RESEARCH DATA ARE PROPERTY PROTECTED BY THE FIFTH AMENDMENT

In the district court, EPA stipulated that Monsanto's grade secret research data are property interests within the ambit of the Fifth Amendment protection against takings. J.S. App. 30a. This is so because the research data are items of commercial value created by the owner's labor and investments. Although state and federal laws clearly protect trade secret property rights, even in their absence these valuable research data would be encompassed by the Fifth Amendment's proscription against the taking of property without just compensation. "The label does not matter, the substance cannot be taken away by the United States even for public use without the owner being made whole." United States v. Smoot Sand & Gravel Corp., 248 F.2d 822, 827-28 (4th Cir. 1957). The term "property" comprises

the group of rights inhering in the citizen's relation to the physical thing, as the right to possess, use and dispose of it.... In other words, it deals with what lawyers term the individual's "interest" in the thing in question.... The constitutional provision is addressed to every sort of interest the citizen may possess.

United States v. General Motors Corp., 323 U.S. 373, 378 (1945).

On appeal, EPA concedes that "while the data remained exclusively in Monsanto's hands any trade secrets contained in

the data would continue to enjoy whatever protections state law afforded." Appellant's Brief at 27. EPA now contends, however, that Monsanto's admitted property rights in its research data were extinguished when Monsanto submitted the data to the Government to obtain registrations. In EPA's words, Monsanto "chose to forego them in order to obtain registrations." Appellant's Brief at 30. In essence, EPA argues that a property owner may be required to surrender constitutionally protected property rights in return for a government license to engage in commerce.

EPA's suggestion that an applicant may be compelled to trade his Fifth Amendment rights for pesticide registrations is incorrect. The United States could not directly condemn and seize an owner's research data without paying just compensation; and what it cannot do directly, it cannot accomplish indirectly. It is settled that the "Government cannot make a business dependent upon a permit and make an otherwise unconstitutional requirement a condition of the permit." Standard Airlines, Inc. v. Civil Aeronautics Board, 177 F,2d 18, 20 (D.C. Cir. 1949). See also Frost & Frost Trucking Co. v. Railroad Commission, 271 U.S. 583 (1926).

In Frost & Frost, a state statute required that a private carrier agree to conditions imposed on public carriers in return for the privilege of using the state's highways. The Court had previously held that private carriers could not be compelled by legislative fiat to become public carriers; and in Frost & Frost, the Court held that what the legislature could not accomplish directly, it could not accomplish by imposing a "condition on a privilege." The state argued that the forced relinquishment of the private carrier's property as a condition precedent to the attainment of a privilege did not offend the Constitution because the private carrier voluntarily submitted itself to the statute's terms; the private carrier was not compelled to "apply" for the statute's coverage. If a private carrier chose to apply for a certificate, however, the state suggested that any conditions could be imposed as prerequisites for granting the privilege.

The Court disagreed, recognizing that the state's argument elevated form over substance. Although the statute spoke of voluntary submission to its terms, the Court recognized the statute as compulsory in every sense: the statute forced the private carrier to make "a choice between the rock and the whirlpool . . . [to] forego a privilege which may be vital to his livelihood or submit to a requirement which may constitute an intolerable burden." 271 U.S. at 593.

The Court stated that although as a general proposition the state could impose such conditions as it saw fit upon a valuable privilege such as a license,

[t]he power of the state in that respect is not unlimited; and one of the limitations is that it may not impose conditions which require the relinquishment of constitutional rights. If the state may compel the surrender of one constitutional right as a condition of its favor, it may, in like manner, compel a surrender of all. It is inconceivable that guaranties embedded in the Constitution of the United States may thus be manipulated out of existence.

271 U.S. at 593-94. See also Western & Southern Life Insurance Co. v. State Board of Equalization, 451 U.S. 648, 657-65 (1981); Thorpe v. Housing Authority of Durham, 386 U.S. 670, 678-79 (1967) (Douglas, J., concurring); Garrity v. New Jersey, 385 U.S. 493, 497-500 (1967).

In the present case, FIFRA requires that applicants surrender Fifth Amendment rights as a condition precedent to receiving a pesticide registration. The issue for this Court is whether this public acquisition of private rights effects a taking. If, as is the case here, it would be a taking if accomplished directly, then it is no less a taking simply because it is accomplished as a "condition on a privilege."

EPA also argues that the doctrines of federal supremacy and preemption dictate that Monsanto's state law rights must yield to the extent that they "conflict" with FIFRA's provisions. Appellant's Brief at 27-28. EPA suggests that because Monsanto's property rights are entirely derived from state law, those rights are not "taken" but rather extinguished by

FIFRA. This fallacious argument would nullify the Fifth Amendment, for most if not all takings could be construed as "redefinitions" of property rights. There is no issue in this case of federal supremacy. FIFRA may supersede state laws, but it cannot supersede the Fifth Amendment. All otherwise valid Commerce Clause legislation is subject to the Fifth Amendment. Kaiser Aetna v. United States, 444 U.S. 164, 174 (1979). If the public interest requires that property rights in research data be expropriated, Congress must accomplish this by eminent domain, in accordance with the Fifth Amendment. Louisville Joint Stock Land Bank v. Radford, 295 U.S. 555, 602 (1935). See also Monongahela Navigation Co. v. United States, 148 U.S. 312, 336 (1893); Addison v. Huron Stevedoring Corp., 204 F.2d 88, 96 (2d Cir.) (Hand, J., concurring), cert. denied, 346 U.S. 877 (1953).

Equally flawed is EPA's argument that trade secret property is protected only against *unlawful* use and disclosure and that FIFRA makes such use and disclosure "lawful." Appellant's Brief at 28-29. Under this circuitous logic Congress could appropriate all private trade secrets at any time, without compensation, merely by providing that it is lawful to use or disclose them. Such a result is not consistent with the Fifth Amendment.

Finally, EPA attempts to characterize the property rights of data owners as merely a "unilateral expectation" of competitive gain based upon the "public acts of government." Appellant's Brief at 31-32. According to EPA, data owners have no cause to complain when the laws are changed to frustrate their unilateral expectations.

This argument mischaracterizes the nature of the property rights at issue. As discussed previously, EPA concedes the existence of property rights in research data while they are in the possession of the owner. These rights are derived from "investment-backed expectations" of the sort that this Court has held to merit Fifth Amendment protection. See Penn Central Transportation Co. v. New York City, 438 U.S. 104, 127, 130, 138 (1978); Pennsylvania Coal Co. v. Mahon, 260 U.S.

393, 413 (1922). They are not gifts bestowed by "public acts of government" but rather the hard-earned fruits of labor and investments made within a legal framework that respects and preserves such rights. They do not vanish simply because one federal law seeks to change the terms of how the United States Government will deal with them.<sup>17</sup>

# II. TRADE SECRET RESEARCH DATA ARE "TAKEN" WITHIN THE MEANING OF THE FIFTH AMENDMENT BY THE PROVISIONS OF FIFRA

Without stating the point in so many words, EPA contends that the taking question in this case should be judged according to the standards and tests for "regulation takings," i.e., cases in which property values are diminished by use restrictions imposed by police power or Commerce Clause legislation. This is the thrust of EPA's contention, because the "bundle of sticks" and "balancing" tests proffered by EPA are for application only to "regulation" takings, and all of the precedents cited by EPA are "regulation" cases. Appellant's Brief at 33-34.

In fact, the FIFRA provisions at issue here are not a "regulation" of the research data, but an outright expropriation of them. For this reason, EPA's arguments and citations on the taking issue are irrelevant.

<sup>&</sup>lt;sup>17</sup> EPA argues that Congress could rescind the FIFRA registration process altogether or prohibit the use of pesticides. Appellant's Brief at 31. Although this may be correct, neither act would necessarily be a taking. What Congress cannot do is transform *private* data into public property by legislative flat and without just compensation. See Frost & Frost, 271 U.S. at 595-96 (state could totally prohibit a business, but could not condition its continuance upon surrender of constitutional rights).

#### A. The FIFRA Provisions Completely Destroy The Value Of The Trade Secret Data

The FIFRA provisions found unconstitutional by the district court permit the unconsented use of the owner's trade secret data to support competitors' registrations, and compel their disclosure. As the Court recognized in *Kewanee Oil Co.* v. *Bicron Corp.*, 416 U.S. 470, 475 (1974), the owner of a trade secret has only the right to exclude others from the enjoyment of the trade secret. The law affords the owner two protections of this right: protection against disclosure and protection against unauthorized use. *See also E. I. du Pont de Nemours & Co.* v. *United States*, 288 F.2d 904, 911 (Ct. Cl. 1961); R. Milgrim, Trade Secrets § 4.01 at 4-2, § 7.07[1] (1983). Just as Monsanto owns research data that consists of "trade secrets under the law of Missouri and consequently has the right to prevent their use and disclosure," other companies' research data enjoy similar protections.

As the Court held in Kaiser Aetna v. United States, 444 U.S. 164 (1979):

[T]he 'right to exclude,' so universally held to be a fundamental element of the property right, falls within this category of interests that the government cannot take without compensation.

Id. at 170-80 (footnote omitted).

The data owner's right to exclude is completely extinguished by these provisions of FIFRA and this valuable property is thus "taken" by the statutory provisions at issue. EPA's argument that there is no "physical invasion" of the trade secret property is misplaced. By disclosing the trade secret data and permitting competitors to use them for any commercial purpose, the data have been "invaded" as thoroughly as in any condemnation.

EPA proposes that "a taking is more readily established where the government regulation destroys all property

<sup>&</sup>lt;sup>18</sup> Ruckelshaus v. Monsanto Co., 104 S. Ct. 3 (1983).

rights," yet fails to recognize what was apparent to the district court: the provisions of FIFRA do destroy the proprietary value of the owner's data. Contrary to the Government's argument, the public disclosure of the data and their unconsented use for the benefit of competitors take not merely strands in a larger bundle of proprietary rights but the essence of the bundle itself. Even under the line of authority relied on by EPA evaluating regulations under the takings clause, the FIFRA provisions must be considered a taking.

# B. Because The FIFRA Provisions Expropriate Private Property, They Constitute A Taking

The "taking" issue in the present case is simpler than the issues presented by cases where true "regulations" diminish the value of private property. This is not a case of regulation, but of expropriation. FIFRA does not regulate an owner's use of his data; it forcibly takes the use of the data and gives it to competitors for their use and benefit. Congress has declared that what was formerly private property be made available to the public. But instead of condemnation and payment of just compensation, Congress elected simply to appropriate the property for others' use. This Congress cannot do.

EPA correctly notes that in taking cases, the "nature of the government action" must be considered as well as "the extent to which the government's action interferes with 'distinct investment-backed expectations.' "Appellant's Brief at 33. EPA apparently construes this dictum as calling for a balancing of the public purpose ostensibly to be served against the harm visited upon affected parties. EPA is confusing the "nature of the action" with the "motive for the action." The correct inquiry concerning the nature of the government's action is not "Why was it done?" but "What was done?" In this case, a focus on what was done discloses that FIFRA does not regulate trade secrets, but rather appropriates them and transfers their use and benefits from their owners to other private parties. Because in this respect FIFRA is an "appropriation," not a regulation, it is a taking per se and there is no "balancing"

to be done. See Loretto v. Teleprompter Manhattan CATV Corp., 458 U.S. 419, 426, 433 (1982). 19

The cases decided by this Court under the "taking" jurisprudence are consistent in application of the distinction between "appropriation" and "regulation." A regulation imposes restrictions on "an owner's use of his own property where deemed necessary to promote the public interest." Loretto, 458 U.S. at 426. By contrast, an appropriation seizes some use of property for the benefit of members of the public. Congress legitimately may prevent a person from using his property in a manner contrary to the public interest. It may not, without infringing rights protected by the Fifth Amendment, appropriate the benefit or use of the property for members of the public without paying for it.

The Court has discussed and applied this pivotal distinction in two recent "appropriation taking" cases. In Kaiser Aetna v. United States, 444 U.S. 164 (1979), the Court rejected the Government's "bundle of sticks" analysis, stressing that

[t]his is not a case in which the government is exercising its regulatory power in a manner that will cause an insubstantial devaluation of petitioners' private property; rather, the imposition [in this case] . . . will result in an actual physical invasion of the privately owned marina. . . And even if the government physically invades only an easement in property, it must nonetheless pay just compensation.

Id. at 180 (citations omitted). In the present case, similarly, the Government is not regulating an owner's use of his research data, but is invading these privately owned data by making the use of them available to the public.

<sup>&</sup>lt;sup>19</sup> See also L. Tribe, American Constitutional Law § 9-3 at 460 (1978) (clearest example of a taking is where the government transfers the legal powers of enjoyment and exclusion that are typically associated with property rights); Kaiser Aetna v. United States, 444 U.S. 164, 179-80 (1979).

The Court employed the same approach in Loretto v. Teleprompter Manhattan CATV Corp., 458 U.S. 419 (1982). The City of New York had granted the cable television company an easement to enter upon certain private buildings to install cable equipment. A New York City landlord challenged this action as a taking of a small part of her property, the part the cable company used to install permanent switching stations. The City attempted to defend the statute with the customary "balancing test" and "bundle of sticks" analyses. The Court brushed these arguments aside as simply irrelevant where the character of the government action was a permanent physical invasion of property-even a very small portion of a large property. 20 458 U.S. at 426, 433-35. The same logic applies in the present case. By enabling competitors to obtain full use of the proprietary research data. FIFRA's action is analogous to the physical invasion of real property.21

<sup>&</sup>lt;sup>20</sup> The Court quoted with approval Professor Michelman's statement that "[t]he one incontestable case for compensation (short of formal expropriation) seems to occur when the government brings it about that its agents, or the public at large, 'regularly' use, or 'permanently' occupy, space or a thing which theretofore was understood to be under private ownership." Loretto, 458 U.S. at 427 n.5.

In the present case, EPA seeks to cause the public and competitor companies to "regularly use" trade secret data that previously were understood to be under private ownership.

<sup>&</sup>lt;sup>21</sup> See also Penn Central Transportation Co. v. New York City, 438 U.S. 104 (1978).

<sup>[</sup>G]overnment actions that may be characterized as acquisitions of resources to permit or facilitate uniquely public functions have often been held to constitute "takings." United States v. Causby . . . is illustrative. In holding that direct overflights above the claimant's land, that destroyed the present use of the land as a chicken farm, constituted a "taking," Causby emphasized that Government had not "merely destroyed property [but was] using a part of it for the flight of its planes." . . . See also Griggs v. Allegheny County, 369 U.S. 84 (1962) (overflights held a taking); Portsmouth Co. v. United States, 260 U.S. 327 (1922) (United States military installations' repeated firing of guns over

In the context of "regulation taking" cases, the Court has emphasized that the character of the governmental action partakes of a restriction on the owner's use. See, e.g., Andrus v. Allard, 444 U.S. 51 (1979). In upholding the regulations (restraints on sale) at issue in Andrus, the Court noted that their effect was to restrict the owner's use of property, not to acquire the property. Id. at 66-67. The Court concluded with a quote from Justice Brandeis:

[T]here was no appropriation of private property, but merely a lessening of value due to a permissible restriction imposed upon its use.

Id. at 67 (emphasis added) (quoting Jacob Ruppert, Inc. v. Caffey, 251 U.S. 264, 303 (1920)). Accord Hamilton v. Kentucky Distilleries & Warehouse Co., 251 U.S. 146, 157 (1919) ("There was no appropriation of the liquor for public purposes."); United States v. Cress, 243 U.S. 316, 328 (1917) ("But it is the character of the invasion, not the amount of damage resulting from it... that determines the question whether it is a taking.").

Here, by contrast, the effect of the FIFRA amendments is precisely to appropriate the use and benefit of trade secret research data. The statute in effect has declared that what was previously private property now is *public* property that all may enjoy equally. This is an appropriation of private property, not a regulation of its use.

EPA makes only a half-hearted attempt to address the "appropriation" issue, stating that "there is also no appropriation of Monsanto's property by the government. The government does not market pesticides, it uses the data. . . . While other companies may obtain a registration on the basis of Monsanto's data [they receive no other rights in the data]." Appellant's

claimant's land is a taking); United States v. Cress, 243 U.S. 316 (1917) (repeated floodings of land caused by water project is a taking). . . .

<sup>438</sup> U.S. at 128 (citations omitted).

Brief at 35. If anything, this statement supports Monsanto's position. EPA argues that there has been no governmental appropriation because the Government "does not market pesticides." Monsanto's competitors do market pesticides, however, and they are the principal beneficiaries of the Government's appropriation of the data.

The nature of the actions authorized by FIFRA makes it clear that the statute effects a taking.

#### III. THE TAKING EFFECTED BY FIFRA IS UNCONSTI-TUTIONAL AND WAS PROPERLY ENJOINED

The district court ruled that the taking imposed by FIFRA contravened the Fifth Amendment. The district court's holding was correct both because FIFRA works a private taking that is unconstitutional regardless of the availability of just compensation and because the Tucker Act is not available in this case to provide just compensation.

#### A. The Taking Of The Trade Secret Research Data Is For A Private Use

The taking of trade secret research data effected by FIFRA is for the direct benefit of other private parties. The unequivocal purpose and result of this section is to provide valuable research data owned by certain companies to their competitors who have not "contributed in money, services, negotiations, skill, forethought, or otherwise," Thompson v. Consolidated Gas Utilities Corp., 300 U.S. 55, 77 (1937). As in Thompson, there is "no more glaring instance of the taking of one man's property and giving it to another" than is found in the forced sharing of an owner's proprietary research data imposed by FIFRA for the benefit of private parties. Id. at 79.

<sup>&</sup>lt;sup>22</sup> The question of whether a taking is for a private or public use is one for judicial resolution as is the question of just compensation discussed hereinafter. See Cincinnati v. Vester, 281 U.S. 439 (1930).

The district court recognized that the "mandatory licensing" of data owners' property to others for their direct benefit cannot satisfy the requirement of a public use and cannot be sustained under the guise of a regulation of commerce. This is not a regulation of property, but rather a taking for the benefit of private parties. See Loan Association v. Topeka, 87 U.S. (20 Wall.) 655 (1874). There the Court stated:

To lay with one hand the power of the government on the property of the citizen, and with the other to bestow it upon favored individuals to aid private enterprises and build up private fortunes, is none the less a robbery because it is done under the forms of law and is called taxation. This is not legislation. It is a decree under legislative forms.

Id. at 664. Just as the taxing power is limited by the Fifth Amendment, so too is the power of Congress to regulate commerce.<sup>23</sup>

#### B. The Taking Is Without Just Compensation

EPA admits that FIFRA itself does not provide just compensation for any takings ("the intra-industry compensation scheme [in FIFRA § 3(c)(1)(D)(ii)] was not meant to provide Monsanto 'just compensation' within the meaning of the Fifth Amendment"). J.S. at 25; Appellant's Brief at 41.<sup>24</sup> As stated

<sup>&</sup>lt;sup>23</sup> See United States v. Cress, 243 U.S. 316 (1917); Monongahela Navigation Co. v. United States, 148 U.S. 312 (1893).

Congress has supreme control over the regulation of commerce, but if, in exercising that supreme control, it deems it necessary to take private property, then it must proceed subject to the limitations imposed by this Fifth Amendment, and can take only on payment of just compensation.

<sup>148</sup> U.S. at 336.

<sup>&</sup>lt;sup>24</sup> Because neither the Government nor Monsanto contends that FIFRA does provide, or was intended to provide, just compensation, the Court should not decide in this case whether the FIFRA compensation scheme violates Article III of the Constitution. See Appellant's Brief at 48-49. The question of whether the FIFRA data use and compensation provisions independently violate Article III was

by the Court in the Regional Rail Reorganization Act Cases, 419 U.S. 102 (1974), "'the issue becomes whether the scheme of the Act, supplemented by the legislative history, sufficiently evidences a Congressional intention to withdraw a remedy that would otherwise exist.' "Id. at 126.

FIFRA clearly evidences the intent of Congress that the private compensation provisions of section 3(c)(1)(D) are to be the sole quid pro quo for the takings effected by the provisions held unconstitutional by the district court. Congress sought to limit any compensation to the data owner only to that provided in section 3(c)(1)(D). Substantive review of such statutory "compensation" determinations is expressly denied to every court of the United States. The statute demonstrates a plain intention to withdraw any otherwise available Tucker Act remedy and to make compensation self-contained in FIFRA itself.

# C. Application Of The Tucker Act To Provide Just Compensation In This Case Would Violate Article I, Section 9, Clause 7 Of The Constitution

Resort to the Tucker Act to provide just compensation in this case would violate Article I, Section 9, Clause 7 of the Constitution. Congress has made no appropriation to pay for a taking of billions of dollars of trade secret research data, and has expressed an intent that the United States not be liable for such data. The Tucker Act therefore cannot supply just compensation for the taking.

Article I, Section 9, Clause 7 provides: "No Money shall be drawn from the Treasury, but in Consequence of Appropria-

decided in Union Carbide Agricultural Products Co. v. Ruckelshaus, 571 F. Supp. 117 (S.D.N.Y. 1983). A direct appeal to this Court was noticed in that case on December 21, 1983. Inasmuch as this issue will be squarely before the Court in *Union Carbide*, and is not necessary to the decision in the present case, the Court should await a full record and thorough briefing on the Article III question and should not decide it here.

tions made by Law. . . . " Pursuant to this grant of constitutional authority. Congress has the exclusive "power of the purse." The federal courts have no power to compel the United States to pay just compensation for a taking, "The absolute control of the moneys of the United States is in Congress and Congress is responsible for its exercise of this great power only to the people." Hart's Case, 16 Ct. Cl. 459, 484 (1880), aff'd sub nom. Hart v. United States, 118 U.S. 62 (1886). Where Congress has not appropriated funds for a particular purpose, neither the executive branch nor the judicial branch can compel payment of funds from the Federal Treasury. See Reeside v. Walker, 52 U.S. 272, 291 (1850) (No officer of the Federal Government is authorized to pay a debt due from the United States, whether or not reduced to a judgment, unless an appropriation has been made for that purpose). Cf. 28 U.S.C.A. § 2517(a) (West Supp. 1983). The Court has not hesitated to apply this principle even in cases in which it worked obvious injustice to creditors of the United States. See, e.g., Sutton v. United States, 256 U.S. 575 (1921); Hooe v. United States, 218 U.S. 322 (1910); United States v. Doullut, 213 F. 729 (5th Cir. 1914).

In cases where Congress has expressly or impliedly acknowledged an obligation to pay just compensation for actions which constitute a taking, the Court has construed the Tucker Act as a means for enforcing this obligation. E.g., Regional Rail Reorganization Act Cases, 419 U.S. 102 (1974). However, the Tucker Act has never been held by this Court to authorize the payment of just compensation where a congressional intent to obligate funds of the Treasury for such a taking could not be found. To extend the Tucker Act in such a fashion would violate Article I by abrogating Congress' authority and responsibility to control the obligation of the funds. Such a doctrine would permit the obligation of federal monies in the absence of an express or implied acknowledgement by

Congress that a taking may occur and that the United States will be liable to pay just compensation if it does occur.25

Application of the Tucker Act to provide just compensation in this case would violate Article I because it would create an obligation upon the United States Treasury under circumstances where the Court cannot conclude that Congress was aware that FIFRA would effect a taking or that it would be willing to appropriate funds to pay the obligation if it were aware of the taking implications.<sup>26</sup> In fact, the language of

If Congress feels morally compelled to appropriate the funds once the taking has occurred and the debt has been created, even though Congress never contemplated that FIFRA would lead to a taking and might well have altered FIFRA to avoid such a result if it had been contemplated, then Congress' prerogatives under Article I will have been abridged.

Congress has many times expressed its ire at acts of government which cause such "moral obligations" to arise which Congress feels

<sup>&</sup>lt;sup>25</sup> The Tucker Act does not contain any express congressional agreement to obligate funds to pay just compensation for actions which constitute a taking. The Act itself merely creates a waiver of sovereign immunity for claims against the United States arising under the Constitution. The Court should not read into this simple waiver of sovereign immunity an intent by Congress to abdicate its Article I duty to control the obligation of funds for actions it did not perceive to be takings and for which it would not have obligated funds if it had been aware of the taking consequences.

<sup>\*\*</sup>Moreover, Congress could refuse to appropriate funds to cover the obligation. Prior to 1977, Claims Court judgments in excess of \$100,000 could not be paid until they had been specifically approved by Congress. 31 U.S.C. § 724a (1976). Section 724a was amended in 1977 to remove the requirement for specific congressional approval, so that judgments in any amount now are paid automatically from the "judgment fund." If inadequate funds are present in the judgment fund, however, no judgments can be paid until more funds are appropriated for that purpose by Congress. Congress could refuse to appropriate more funds, or could direct that the additional funds not be spent for a particular purpose, e.g., FIFRA takings.

FIFRA compels the conclusion that Congress did not intend to obligate federal funds for this purpose. The FIFRA compensation scheme provides that the sole recourse for the actions that constitute the taking shall consist of arbitration between private persons in which the Government is not a party.

In the cases in which the Court has permitted recourse to the Tucker Act to provide just compensation for threatened takings, Article I problems did not arise. In these cases, there was congressional awareness that the actions it was authorizing would lead either to taking liability or, at a minimum, to substantial obligations of funds from the Federal Treasury. See, e.g., Regional Rail Reorganization Act Cases, 419 U.S. 102 (1974) (Congress provided a fund to pay just compensation to owners of railroad property); Duke Power Co. v. Carolina Environmental Study Group, Inc., 438 U.S. 59 (1978) (Congress provided that the United States would be liable in the event of a nuclear plant failure); Hurley v. Kincaid, 285 U.S. 95 (1932) (Congress provided funds for flood-control project construction which resulted in diminution of the value of land). In each of these cases, Congress demonstrated an intent to obligate federal funds for the programs which gave rise to alleged takings. Under these circumstances, the Court did not authorize obligations by permitting recourse to the Tucker Act; Congress had already authorized the obligations when it mandated the acts in question with awareness of their federal fiscal implications.27

that it must pay although constitutionally it cannot be compelled to do so. The avoidance of such "moral obligations," which abridge Congress' Article I powers, has been a major objective of Congress, leading to the passage and repeated strengthening of the Anti-Deficiency Act, 31 U.S.C. § 665 (1976 & Supp. V 1981). For a discussion of the background of the Act, see Fenster & Volz, The Antideficiency Act: Constitutional Control Gone Astray, 11 Pub. Cont. L.J. 155, 156-62 (1979).

Further, most of the "Tucker Act cases" relied upon by the Government were either cases where the taking had already occurred, so there was no question of injunction, e.g., United States v. Causby, 328 U.S. 256 (1946); Yearsley v. W.A. Ross Constr. Co., 309

In the case of FIFRA, Congress did not intend to obligate any federal funds to pay for the use or disclosure takings effected by the statute. To the contrary, Congress intended that only private concerns be involved in compensation adjudications, and it withdrew the jurisdiction of federal courts over compensation awards. Where, as in the present case, there is an imminent and substantial taking, with no evidence of congressional intent to obligate the United States for acts that might result in a taking, to proceed based on the availability of the Tucker Act would violate Article I by creating an unintended and unauthorized liability.

Other cases decided by the Court are consistent in result with the Article I requirement that Congress must make the decision to obligate funds. In such cases, the Court has struck down congressional legislation and instructed Congress to consider the implications of its actions, and if it chooses to proceed, to do so by eminent domain. Louisville Joint Stock Land Bank v. Radford, 295 U.S. 555, 602 (1935). See also Perry v. United States, 294 U.S. 330 (1935); Lynch v. United States, 292 U.S. 571 (1934).

U.S. 18 (1940), or cases in which there was no imminent taking but only the speculative possibility of a taking at some undetermined future date if certain contingencies arose, e.g., Duke Power Co. v. Carolina Environmental Study Group, 438 U.S. 59 (1978); Regional Rail Reorganization Act Cases, 419 U.S. 102 (1974).

In the former group of cases, the "taking" had already occurred and the federal financial obligation thereby incurred, so there was no Article I issue raised by the Court's recognizing the existence of the federal obligation. In the latter group of cases, (1) there was no certainty of a taking with its concomitant federal obligations, so the Court did not create obligations when it refused to strike down the acts; (2) the fact that the taking, if any, was in the future meant that Congress would have an opportunity in the meantime to change the legislation to avoid the taking, so preserving its Article I prerogatives, see Rail Act Cases, 419 U.S. at 149 n.36, 179-80 (Douglas, J., dissenting); and (3) Congress had in each case provided for substantial federal obligations, thus evincing its intention to exercise its Article I powers.

In Louisville Bank, as here, the nature of the congressional action was a sweeping reallocation of intangible property rights (relating to liens and foreclosures) from their owners (banks) to other persons (primarily small farmers). In that case too, Congress believed it could accomplish its goal by redistributing private rights without paying for them. The Court held the offending provisions void, and Congress was thereby given the opportunity to consider whether it wished to pursue its objective of mortgage relief by using its eminent domain power, whether it could accomplish its goal in some other, less expensive manner, or whether it would prefer to abandon its goal. The same result would follow in this case from an affirmance of the district court's judgment.

D. The Claims Court Does Not Have Constitutional Power To Adjudicate Taking Claims, And There Is No Appropriate Forum For Data Originators To Invoke A Tucker Act Remedy

Prior to enactment of the Federal Courts Improvement Act of 1982, Pub. L. No. 97-164, 96 Stat. 25, constitutional taking claims were adjudicated in the United States Court of Claims. The Court of Claims was constituted under Article III of the Constitution, *Glidden Co. v. Zdanok*, 370 U.S. 530 (1962), and its judges were accorded the life tenure and guarantee against diminution in salary afforded by Article III.

Under the Federal Courts Improvement Act, however, the adjudication of taking claims is vested in the newly created United States Claims Court. Congress constituted the Claims Court as a legislative court under Article I of the Constitution, its judges serving fifteen-year terms, subject to reappointment by the President. 28 U.S.C.A. §§ 171(a), 172(a) (West Supp. 1983). Thus adjudication of taking claims, traditionally entrusted to an Article III judicial forum, is now within the jurisdiction of a non-Article III court.

In Northern Pipeline Construction Co. v. Marathon Pipe Line Co., 458 U.S. 50 (1982), a plurality of the Court held that the Bankruptcy Reform Act of 1978, which created a system of bankruptcy courts as adjuncts to federal district courts, violated the constitutional requirement that judicial power must be exercised by courts having the attributes prescribed in Article III. The Court found unconstitutional the delegation by Congress of powers traditionally held by federal district court judges, to non-Article III bankruptcy court judges. The Court declared that, except in certain limited circumstances, the judicial power of the United States is constitutionally entrusted to, and must be exercised by, judges who have the attributes guaranteed by Article III. Northern Pipeline was premised in part on the prior decision in Crowell v. Benson, 285 U.S. 22 (1932), in which the Court held that cases involving enforcement of constitutional rights must be heard by Article III tribunals:

We think that the essential independence of the exercise of the judicial power of the United States in the enforcement of constitutional rights requires that the Federal court should determine such an issue upon its own record and the facts elicited before it.

285 U.S. at 64. The Court emphasized the need for an Article III determination in "confiscation" cases in particular:

In cases brought to enforce constitutional rights, the judicial power of the United States necessarily extends to the independent determination of all questions, both of fact and law, necessary to the performance of that supreme function. The case of confiscation is illustrative, the ultimate conclusion almost invariably depending upon the decisions of questions of fact. This court has held the owner to be entitled to "a fair opportunity for submitting that issue to a judicial tribunal for determination upon its own independent judgment as to both law and facts." Ohio Valley Water Co. v. Ben Avon Borough, supra. See, also, Prendergast v. New York Telephone Co., 262 U.S. 43, 50; Tagg Bros. & Moorhead v. United States, supra; Phillips v. Commissioner, 283 U.S. 589, 600.

285 U.S. at 60.

See also Pacemaker Diagnostic Clinic, Inc. v. Instromedix, Inc., 712 F.2d 1305 (9th Cir. 1983), reh'g granted, Nos. 82-3152, 82-3182 (9th Cir. Oct. 20, 1983).

The Claims Court suffers from the same constitutional defect that was found fatal in Northern Pipeline and Crowell. To the extent that the Claims Court is vested with exclusive jurisdiction over taking cases, it intrudes upon the constitutional jurisdiction of Article III courts. Northern Pipeline and Crowell dictate that an Article I court may not, consistent with the Constitution's separation of powers, be granted such jurisdiction. Data originators cannot assert their taking claims in the Claims Court, and there is no other forum available to them. The taking is therefore without just compensation.

#### CONCLUSION

The amici urge the Court to affirm the holding of the district court that the FIFRA use and disclosure provisions effect a taking of property for private use and without just compensation in violation of the Fifth Amendment.

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Dated: January 19, 1984

NOV 28 1983

In The

## Supreme Court of the United States

October Term, 1983

WILLIAM D. RUCKELSHAUS, ADMINISTRATOR, UNITED STATES ENVIRONMENTAL PROTECTION AGENCY,

Appellant,

VS.

#### MONSANTO COMPANY,

Appellee.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF MISSOURI

BRIEF OF THE AMERICAN ASSOCIATION FOR THE ADVANCEMENT OF SCIENCE, THE AMERICAN PUBLIC HEALTH ASSOCIATION, AND THE SOCIETY FOR CLINICAL ECOLOGY AS AMICI CURIAE IN SUPPORT OF APPELLANT

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## TABLE OF CONTENTS

	P
Inte	rests of Amici
Sum	mary of Argument
	ument:
I.	Public Disclosure And Peer Review Are Essential To Ensure The Integrity And Objectivity Of Scientific Research.
П.	Public Disclosure Of Data Is Particularly Important In The Pesticide Regulatory Process In Order To Ensure Protection Of Public Health And Safety.
III.	Congress' Decision To Allow Public Disclosure Of Pesticide Data Should Not Be Overturned
Con	elusion
CASI	TABLE OF AUTHORITIES
	ted States v. Calandra, No. 81-CR-325 (N. D. l. 1980)
STA	TUTES AND REGULATIONS:
7 U.	.S. C. § 136w(e) (1980)
46 I	Fed. Reg. 61502-05 (Dec. 17, 1981)
Отн	ER AUTHORITIES:
B. I	Barber, Science and the Social Order 91 (1952)
Ber	kner, "Secrecy and Scientific Progress," 123 cience 783 (1956)
	Bok, Secrets: On the Ethics of Concealment and Revelation 155 (1982)
	Broad & N. Wade, Betrayers of the Truth 17-

## TABLE OF AUTHORITIES—Continued

	Pages
123 Cong. Rec. 25711 (1977)	20
123 Cong. Rec. 36008 (1977)	20
128 Cong. Rec. H5679-89 (daily ed. Aug. 11, 1982)	9, 19, 20
Drug Regulation Reform Act of 1978: Hearings on S. 2755 Before the Subcomm. on Health and Scientific Research of the Senate Comm. on Human Resources, 95th Cong., 2d Sess. 841 (1978)	_8, 9, 19
EPA, Office of Pesticide Programs, Summary of the IBT Review Program (July 1983)	17
EPA, Office of Pesticide Programs, IBT Track- ing System Report (August 30, 1983)	17
Fraud in Biomedical Research: Hearings Before the Subcomm. on Investigation and Oversight of the House Comm. on Science and Technology, 97th Cong., 1st Sess. (1981)	5,7
W. Hagstrom, The Scientific Community 91 (1965)	8
Hearings on H. R. 3818 Before the Subcomm. on Dep't Operations, Research, and Foreign Agri- culture of the House Comm. on Agriculture, 98th Ong., 1st Sess. (Nov. 2, 1983)	,18
"HED Reviewers Reassigned Because of 'Cut and Paste' Audit Results," Pesticide and Toxic Chemical News, pp. 15-16 (October 5, 1983)	18
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McGarity & Shapiro, "The Trade Secret Status of Health and Safety Testing Information; Reforming Agency Disclosure Practices," 93 Harv. L. Rev. 837 (1980)	_12, 14

### TABLE OF AUTHORITIES-Continued

	Pages
R. Merton, "Normative Structure of Science," in The Sociology of Science 266 (1973)	6
R. Merton & H. Zuckerman, "Institutionalized Pat- terns of Evaluation in Science, "in <i>The Sociol-</i> ogy of Science 460 (1973)	7
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President's Science Advisory Comm., Panel on Chemicals and Health, Report on Chemicals and Health (1973)	9
Schneider, "Faking It: The Case Against Industrial Bio-Test Laboratories," 4 The Amicus Journal 114 (Spring 1983)	= 16
S. Rep. No. 334, 95th Cong., 1st Sess. 13 (1977)	20
"Story of 'Safe' Pesticides Ends as Classic Case of Misuse," New York Times, March 4, 1980, p. C1	14

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#### INTERESTS OF AMICI\*

The American Association for the Advancement of Science ("the Association") was founded in 1848 and incorporated in 1874. Its objects are to further the work of scientists, to facilitate cooperation among them, to foster scientific freedom and responsibility, to improve the effectiveness of science in the promotion of human welfare, and to increase public understanding and appreciation of the importance and promise of the methods of science in human progress.

All parties have consented to the submission of this brief.
 Written letters of consent will be on file with the Clerk.

The interest of the Association in this case is to secure those essential conditions required to preserve integrity, accountability and responsibility in the exercise of scientific judgments in regulatory proceedings affecting public health and safety. The standards of scientific responsibility require the bases for scientific claims or assertions to be disclosed in a manner conducive to fully informed and open examination and evaluation. This case presents issues that affect in a fundamental way the Association's concerns for the preservation and integrity of scientific knowledge and the full use of that knowledge in the administration of regulatory powers involving health and safety.

The American Public Health Association ("APHA"), a non-profit organization founded in 1872, is the oldest and largest professional public health society in the world, with a combined national and affiliate membership of over 50,000 health professionals. APHA works to promote the health of the American people by encouraging a safe and healthful environment, launching public health education programs, advancing the availability of health services, and publishing numerous materials reflecting developments in public health, including dissemination of environmental information.

APHA is concerned about the potential hazards to humans and the environment posed by the use of pesticide chemicals. Increased public education about the dangers of pesticides is crucial in order to minimize these hazards. Public disclosure and peer review of pesticide health and safety data, in particular, is essential to protect humans and the environment.

The Society for Clinical Ecology ("the Society") is a national non-profit organization of physicians whose practices include treating patients with chronic and acute sensitivities to foods, chemicals and other allergenic substances. Members of the Society stress a very comprehensive environmental analysis of the etiology of their patients' afflictions. They test their allergic patients for a wide range of possibly offending substances. Their testing and treatment modalities are based on the most modern understanding of the human immune system and consequently are very successful.

Members of the Society find an increasing number of their patients to be allergic to various chemicals and particularly to both commercial and domestic pesticides. Many of their patients have become extremely sensitive to a host of substances as a result of varying exposures to pesticides, due to a phenomenon called immune function disregulation. Some have become so sensitive as a result of contact with pesticides that their ability to move freely in modern society has become severely limited.

The members of the Society for Clinical Ecology treat the victims of pesticide poisoning. In order for them to adequately treat these patients, it is essential for these doctors to be able to have access to the data involved in the pesticide regulatory decision-making process of the United States Environmental Protection Agency. It is also important for this same regulatory process that it benefit from the clinical experience of these doctors, who know first-hand what harm various pesticides can cause, even to persons with no previous histories of chemical sensitivities.

#### SUMMARY OF ARGUMENT

This appeal raises the critical issue of whether the public may have access to the health and safety studies used by the United States Environmental Protection Agency (EPA) to make pesticide regulatory decisions. Public disclosure and independent peer review of data are essential to ensure the integrity and validity of scientific research. Public disclosure of research results is also a fundamental norm in our scientific and political communities.

The district court's holding creates an anomalous situation in which the data relied upon to make crucial pesticide regulatory decisions are exempt from the public disclosure and peer review processes that operate in the broader scientific community. There are numerous instances in which EPA's closed regulatory scheme has failed to reveal fraudulent and inaccurate pesticide data, resulting in serious risks to public health and the environment. Public disclosure of such data would increase the likelihood of detecting and correcting regulatory errors through the peer review process. Congress amended the federal pesticide law in 1978 in recognition of this problem, and its decision to allow public disclosure of health and safety data was well within its constitutional powers and should not be overturned.

### ARGUMENT

I. Public Disclosure And Peer Review Are Essential To Ensure The Integrity And Objectivity Of Scientific Research.

In order to promote the integrity and objectivity of scientific research, the scientific community relies heavily

on an internal, "self-policing" system known generically as "peer review." Through this process, independent scientists review and criticize the procedures, data analyses, and conclusions of scientific research before reports of the results are published or otherwise relied upon. The process can continue after publication as other scientists subject the results to the ultimate test of reproducibility. Peer review allows for the expression of a broad spectrum of theories and viewpoints to ensure scientific accuracy and objectivity. Without full public disclosure of the research methodology, raw data and results, however, the peer review process cannot operate effectively. The district court's judgment effectively precludes this process from occurring at all.

The peer review process in the scientific community embodies at least three distinct checks on reliability and validity of results. First, applications for funding and approval of a project are carefully reviewed and assessed by rotating panels of advisers prior to project approval. Second, scientific journals request independent "referees" to measure the finished research products against scientific standards of quality and acceptability, to determine whether the research merits publication. Third, assuming the research passes these tests and is published, it is subject to an endless informal review process in which

<sup>&</sup>lt;sup>1</sup>See, e.g., Fraud in Biomedical Research: Hearings Before the Subcomm. on Investigation and Oversight of the House Comm. on Science and Technology, 97th Cong., 1st Sess. 33-35 (1981) (statement of Donald S. Fredrickson, M.D., Director, National Institutes of Health) (hereinafter cited as Biomedical Research Hearings); id. at 166-67 (testimony of Dr. William F. Raub, Associate Director, National Institutes of Health); W. Broad & N. Wade, Betrayers of the Truth 17-18, 61-62. 89 (1982).

the work is read, considered, tested and at times replicated to ensure accuracy. Throughout, the process is characterized by full public disclosure of the techniques used and the results obtained. Openness is the essential ingredient for this time-honored process.

Public disclosure and peer review of data serve a number of critical functions in the scientific community and in our political system. Perhaps the most important application of peer review is in the regulatory framework where scientific decisions are made and reviewed. In this context, disclosure of the factual basis for regulatory decisions is essential to allow informed public participation and to promote careful and balanced decision-making. Secrecy, on the other hand, impugns the integrity of the decision-making process.

First and foremost, peer review is the most basic and effective means for ensuring accuracy in science. There can be little dispute that peer review and public disclosure of data have played a critical role in weeding out bad science from good science. Robert Merton, a recognized authority in the sociology of science, has attributed the rarity of fraud in science to "certain distinctive characteristics of science itself. Involving as it does the verifiability of results, scientific research is under the exacting scrutiny of fellow experts. . . . [T]he activities of scientists are subject to rigorous policing, to a degree perhaps unparalleled in any other field." According to Dr. Philip Handler, former President of the National Academy of Sciences, "[t]he system succeeds in policing itself as it

<sup>&</sup>lt;sup>2</sup>R. Merton, "The Normative Structure of Science," in The Sociology of Science 266, 276 (1973).

does . . . not so much out of extraordinarily intrinsic honesty of those individuals who elect careers in science, but out of the fact that the entire system operates on the record." It is no exaggeration to say that "[t]he greatest protection in science is the critical review and analysis of the published data and procedures by the scientist's peers."

In addition to the functional, self-policing role played by peer review, full disclosure of techniques and results is a basic element in the scientific method. "The scientific method requires that all research work be open to critical examination and testing by researchers in the field." According to ethicist Sissela Bok, the norm of openness in science springs "from a recognition of the damage that secrecy can do to thinking and to creativity, and thus to every form of scientific inquiry." As stated by Donald Kennedy, then-Commissioner of the Food and Drug Administration (FDA):

[The peer review] system is at the heart of the scientific process; it is a fundamental requirement of science that the hypotheses and conclusions of one

<sup>&</sup>lt;sup>3</sup>Biomedical Research Hearings, supra note 1, at 13.

<sup>41</sup>d. at 66 (testimony of Dr. Ronald Lamont-Havers, Director of Research, Massachusetts General Hospital). See generally, id. at 65-68; id. at 83, 90 (testimony of Dr. Philip Felig, Yale School of Medicine); id. at 353-55 (testimony of Dr. Patricia Woolf, Princeton University); R. Merton & H. Zuckerman, "Institutionalized Patterns of Evaluation in Science," in The Sociology of Science, supra note 2, at 460-96.

<sup>&</sup>lt;sup>5</sup>Pigman & Carmichae], "An Ethical Code for Scientists," 111 Science 643, 645 (1950).

<sup>6</sup>S. Bok, Secrets: On the Ethics of Concealment and Revelation 155 (1982).

scientist be subjected to public examination, criticism, and debate by other scientists before their validity is accepted. Such public comment depends on the availability of the analytical and empirical bases for the hypotheses and conclusions. If the underlying procedures and data cannot be examined by others, the scientific community cannot be confident of, nor eventually accept, the validity of the conclusions reported by the discoverer. Secrecy is antithetical to good science.'

Full disclosure of scientific research is necessary for scientific progress and innovation. Sociologist Bernard Barber has argued that "informal discussion among scientists of new work and new ideas" is "essential to all scientific innovation." Secrecy "restricts the dissemination of new and possibly important techniques," both within the scientist's own field and within related fields.

Restrictions on public disclosure and review of data may not only impede advances in theoretical science, but may also preclude efforts to protect public health. As stated by the President's Science Advisory Committee in 1973, "[n]ot allowing the academic research community access to the retained results of [drug] safety testing is believed to have adversely affected progress in the understanding of the presence or absence of unfortunate ef-

<sup>&</sup>lt;sup>7</sup>Letter from FDA Commissioner Donald Kennedy to Senator Edward M. Kennedy (May 5, 1978), reprinted in Drug Regulation Reform Act of 1978: Hearings on S. 2755 Before the Subcomm. on Health and Scientific Research of the Senate Comm. on Human Resources, 95th Cong., 2d Sess. 841, 842 (1978) (emphasis added) (hereinafter cited as Kennedy Letter).

<sup>8</sup>B. Barber, Science and the Social Order 91 (1952).

<sup>9</sup>W. Hagstrom, The Scientific Community 91 (1965).

fects of chemicals on people."10 The concerns of groups like the March of Dimes with respect to limitations on free disclosure and peer review are worth emphasizing:

The March of Dimes believes that putting a restriction on public information would severely limit the free exchange of scientific thought; even decrease the amount of scientific research so often fostered by this process of peer review. Limiting research will postpone, if not prevent, the discovery of causes and cures for the many birth defects which still afflict our infants and children. It may expose the unborn to harmful chemicals because these chemicals cannot be subject to peer review by the scientific community.<sup>11</sup>

Public disclosure of health and safety data is particularly important in a democratic political system. It is "a basic principle of our political system . . . that people affected by governmental decisions have a right to know the basis on which they are made." Barring public scrutiny of the information underlying regulatory decisions removes a vital check on governmental policymaking.

The secrecy of technological information is incompatible with the public policy function of a democracy. In our elective system, in the absence of public debate, there is no certainty that policy-making officials will possess the competence required for wise decisions or that they will even understand what elements of information are important. Moreover, even assum-

<sup>&</sup>lt;sup>10</sup>President's Science Advisory Comm., Panel on Chemicals and Health, Report on Chemicals and Health (1973), reprinted in Kennedy Letter, supra note 7, at 842.

<sup>&</sup>lt;sup>11</sup>Letter from March of Dimes to Members of Congress, quoted at 128 Cong. Rec. H5687 (daily ed. August 11, 1982) (Rep. Daschle).

<sup>12</sup>Kennedy letter, supra note 7, at 841.

ing the wisdom of policy-making officials, sound policy results from the careful examination of facts by the people of a nation in light of their diverse training and interests. Secrecy prevents the discussion necessary to such examination.<sup>13</sup>

Even if individual members of the public only rarely request to see the health and safety data that federal regulatory agencies collect, public availability of that data plays an important legitimizing role. The fact that any independent scientist may at any time scrutinize carefully the results of tests that support a product's license makes the safety-related decisions of the regulatory agency much more acceptable to the affected public. Failure to allow such scrutiny, on the other hand, breeds skepticism and ultimately contempt for the regulatory process.

#### II. Public Disclosure Of Data Is Particularly Important In The Pesticide Regulatory Process In Order To Ensure Protection Of Public Health And Safety.

In contrast to the open nature of most scientific research, the regulatory framework in which pesticide health and safety data are generated and analyzed lacks the multiple checks and balances of an open peer review system. Since the pesticide industry itself sponsors nearly all of the research, the initial peer review process of scrutinizing applications for government funding is entirely circumvented. The resulting studies are rarely published, thereby precluding independent scientists from reviewing or attempting to replicate the work. If the studies submitted to EPA may not be disclosed, the data and test methodology never enter the normal peer review channels,

<sup>&</sup>lt;sup>13</sup>Berkner, "Secrecy and Scientific Progress," 123 Science 783, 786 (1956).

and therefore are not subject to scrutiny by independent scientists.<sup>14</sup>

Before allowing the use of a pesticide in the United States, EPA must engage in a rigorous risk-benefit balancing process to ensure that pesticides do not pose an unreasonable risk to humans or to the environment. In order to make a fully informed decision, EPA requires pesticide registration applicants to submit a variety of health and safety studies. Certain of these studies are used by the agency to assess the chemical's potential to cause adverse effects to humans including cancer, birth defects, nerve damage and genetic mutations.

The studies submitted to EPA consist primarily of the results of animal feeding and exposure tests. With few exceptions, these tests are conducted exclusively by the pesticide manufacturers and private laboratories under contract to them. Interpreting these tests is often extremely controversial. Reasonable minds can differ with respect to the nature of the observed results (raw data), the extrapolation of such results to humans and

<sup>14</sup>A limited formal procedure for review of certain pesticide data does exist, but the process does not purport to substitute for independent peer review made possible by disclosure of data. See 7 U. S. C. § 136w(e) (1980). EPA's procedures provide for mandatory peer review only of those studies sponsored or undertaken by the agency, not of the vast majority of studies prepared by industry. Industry studies considered by the agency to be "pivotal" will only be peer reviewed "at the discretion of the agency;" whereas other "supporting studies . . . will generally not be peer reviewed." As a result, "there will be many important studies done by industry and by the public sector which the Agency will not submit for peer review." See 46 Fed. Reg. 61502-05 (Dec. 17, 1981). Moreover, the formal review process is limited to a select group of scientists and does not provide for full public disclosure and independent scientific review of data.

the regulatory implications of the results. Industry scientists, not surprisingly, generally advocate an interpretation that will allow their products to be marketed with a minimum of regulatory restrictions.<sup>15</sup> With unsettling frequency, the health and safety data that the pesticide industry provides to support its products have been found to be misleading and, in some cases, entirely fraudulent.

Unless the health and safety studies are made available to the public, the only opportunity for scientific review is by agency personnel. Given staff and funding limitations, however, agency scientists cannot be expected to evaluate thoroughly every health and safety study submitted on behalf of a pesticide. Moreover, a one-time agency examination of completed research cannot substitute for review by a diverse group of independent peers over a period of time, which would be possible if data were disclosed. When agency scientists are essentially confined to dialogue with industry scientists—who of necessity must assume an advocacy role—they are deprived of the scientific pluralism that is crucial to informed scientific judgment.

Until 1978, the process of pesticide testing was effectively shielded from any open peer review. Under the rubric of "trade secrets," the pesticide industry successfully obtained a closed system which precluded public scrutiny of its health and safety data. The history of this closed process is replete with incidents in which the registrations of widely-used toxic pesticides have been based upon false and, in some cases, fraudulent data.

<sup>&</sup>lt;sup>15</sup>See McGarity & Shapiro, "The Trade Secret Status of Health and Safety Testing Information: Reforming Agency Disclosure Practices," 93 Harv. L. Rev. 837, 840-41 (1980).

When government scientists cannot participate in the normal system of peer review that scientists use to evaluate their research, it significantly hampers their ability to make judgments necessary to protect the public.

Unlike the numerous opportunities for peer review in the scientific community, there has been virtually no independent scientific scrutiny of the health and safety data that often serve as the sole basis for EPA's pesticide regulatory decisions. As a result of this closed process, a number of serious problems have remained undetected for years, ranging from scientific inaccuracies, to incorrect or biased interpretations, to outright fraud or fabrication of the data. The following examples demonstrate the strong public interest in full disclosure and peer review of pesticide health and safety test data.

Heptachlor. EPA's decision to register a pesticide for a particular use depends almost exclusively on a one-time review of the health and safety data submitted by the pesticide manufacturer. After a product is approved, the agency rarely has the time and resources to re-evaluate the original test data in light of changing facts or newer scientific evaluational criteria. In some cases, deficiencies in the tests submitted in support of a pesticide have only been discovered years after the pesticide was registered.

In the case of the pesticide heptachlor, an earlier industry interpretation of data remained unexamined for years in the government's files, even though the scientific community's interpretational criteria had changed significantly. Heptachlor was initially registered based on the manufacturer's data that purported to show that the chemical did not cause cancer in laboratory animals. Fifteen years later, a re-evaluation of the same data by independent scientists—supported by new tests—indicated that heptachlor was carcinogenic. Between the initial approval of heptachlor and its final removal from the market fifteen years later, the public was exposed to high levels of the chemical. The manufacturer was indicted in 1977 for concealing key scientific results on the carcinogenicity of heptachlor. However, the case was dismissed on procedural grounds.

Temik. Without mandatory disclosure of pesticide data, the agency may fail to obtain key information that would enable it to assess the test data more thoroughly. In the case of the pesticide Temik (R), agency scientists overlooked the narrow and misleading assumptions underlying one key study. Based on these limited assumptions, the study erroneously predicted that use of the product was safe.

The carbamate pesticide Temik or aldicarb, licensed for use in the mid-1960s, is one of the most acutely poisonous substances registered for use on food. At that time, the industry-submitted tests allegedly demonstrated that after application to the soil, Temik would biodegrade to a harmless substance before reaching the groundwater. However, in 1979, Temik was detected at dangerous levels in the groundwater of some areas on Long Island. Long Island's groundwater is the sole source of drinking water

<sup>16/</sup>d. at 841.

<sup>&</sup>lt;sup>17</sup>See, e. g., "Story of 'Safe' Pesticide Ends as Classic Case of Misuse," New York Times, March 4, 1980, p. C1.

for nearly three million people. The manufacturer later admitted that its groundwater leaching studies had failed to analyze the effects of pesticide use in regions, like Long Island, with sandy soils and shallow groundwater. Since 1979, Temik has also been detected in groundwater and drinking water in Florida, Maine, Wisconsin, California, North Carolina, Virginia and Arizona.

In retrospect, many are surprised that government officials did not foresee the Long Island groundwater contamination by Temik, given the widespread knowledge about Long Island's geologic composition and the facility of numerous substances to percolate or leach through these soil types. However, EPA scientists were largely isolated from routine consultation with the scientific community, because they could not disclose the data on Temik's environmental fate. It is entirely plausible that scientists or members of the public with knowledge of local conditions could have alerted EPA to the flawed assumptions of the industry's study, thereby avoiding a serious public health hazard.

Industrial Bio-Test Laboratories. Another problem resulting from the absence of peer review of pesticide data is that agency scientists may not be capable of weeding good science from bad science. This inability may be the result of unreasonable work loads or of the lack of routine communications with independent scientists. The most glaring example of this problem involves one of the nation's oldest and largest independent laboratories, Industrial Bio-Test Laboratories (IBT).

In 1976, Dr. Adrian Gross, an FDA investigator at the time, became suspicious of several IBT studies be-

cause they seemed to prove the safety of pesticide and drug products a bit too convincingly. When Dr. Gross reviewed some of IBT's raw data he discovered an unusual term, "TBD," or "too badly decomposed," which was used to indicate that animals had died and rotted in their cages before yielding any useful information. The fact that the animals were so poorly observed did not speak well of the carefulness and thoroughness of IBT's research efforts. Yet, the results submitted to the agency did not report this shoddy technique. Dr. Gross' observations led to other investigations of IBT that revealed other examples of falsified research, including substituting fresh test animals for ones that died during the course of an experiment, transferring data from one IBT experiment to another study, and using data from a study at another lab in IBT reports.18 As a result, IBT's top officials were recently convicted in federal court of conducting fraudulent research with respect to four chemicals.19

The criminal conviction, however, represents only the tip of the iceberg. In July 1983, EPA released a long-awaited report summarizing the results of a seven-year investigation of IBT. The report uncovered what may be the most extravagant use of fraud in scientific history. The data in the report (and in an updated version) indicate that only three percent of the 803 IBT tests on chronic health effects (cancer, birth defects, adverse reproductive effects, nerve damage and genetic mutations) are val-

<sup>&</sup>lt;sup>18</sup>See Schneider, "Faking It: The Case Against Industrial Bio-Test Laboratories," 4 The Amicus Journal 114 (Spring 1983); Marshall, "The Murky World of Toxicity Testing," 220 Science 1130 (1983).

<sup>&</sup>lt;sup>19</sup>United States v. Calandra, No. 81-CR-325 (N. D. III. 1980).

id and sufficient to support pesticide registration.<sup>20</sup> The validity of a number of IBT studies still remain to be determined. In the meantime, between 140 and 182 separate pesticide active ingredients registered with IBT data remain in use.<sup>21</sup> While the safety of these chemicals is unknown to EPA, the public continues to be exposed to them as residues in their food and drinking water, in home use pesticide products, in the workplace, and throughout the environment.

It is impossible to know whether the fraud and inaccuracies in the IBT studies would have been uncovered sooner if the public had been given access to the raw data underlying these studies as they were reported to EPA. The likelihood that the studies would have been subject to peer review, however, would have been a powerful disincentive to falsify and cheat. Without the threat of full public disclosure, the company risked detection only by overworked agency scientists, a gamble it was willing to take.

Harvade. The previous examples have demonstrated that EPA is incapable of ensuring the integrity of health and safety data on its own. Perhaps the most egregious example of this failure is the recent discovery that some EPA scientists reviewing industry-submitted studies have merely cut and pasted summaries from those studies onto agency stationery, and labeled the re-typed document,

<sup>&</sup>lt;sup>30</sup>EPA, Office of Pesticide Programs, Summary of the IBT Review Program (July 1983); EPA, Office of Pesticide Programs, IBT Tracking System Report (August 30, 1983).

<sup>&</sup>lt;sup>21</sup>The EPA reports contain a number of inconsistencies; therefore, it is difficult to determine the precise number of pesticides registered with IBT data.

"Review of. . . ." These cut-and-paste reviews suggest that overworked agency scientists have uncritically accepted the accuracy, completeness, and conclusions of the industry-submitted data.<sup>22</sup>

One example of this treatment is the chemical Harvade. The agency toxicologist assigned to Harvade reviewed the studies by the cut-and-paste method. Subsequently, the chemical was approved by EPA, and it went on sale in 1982. Several weeks after its approval, another agency scientist spotted discrepancies between the earlier review and his own findings on Harvade's toxicity. Shortly thereafter, the cut-and-paste copying was discovered and the chemical is now being re-evaluated. In the meantime, Harvade remains on the market.<sup>23</sup>

#### III. Congress' Decision To Allow Public Disclosure Of Pesticide Data Should Not Be Overturned.

There is every reason to believe that public disclosure and peer review would promote the integrity and objectivity of scientific studies in the context of pesticide regulatory decision-making. Dr. Donald Kennedy has emphasized that the "validity and credibility of [regulatory]

<sup>&</sup>lt;sup>22</sup>See Hearings on H. R. 3818 Before the Subcomm. on Dep't Operations, Research, and Foreign Agriculture of the House Comm. on Agriculture, 98th Cong., 1st Sess. (Nov. 2, 1983) (statement of William D. Ruckelshaus, EPA Administrator).

<sup>&</sup>lt;sup>23</sup>EPA has contracted with Battelle Memorial Institute to conduct an analysis of its Office of Pesticide Programs. Preliminary results indicate that cut-and-paste review are much more prevalent than originally thought. Six EPA staff members have been reassigned to tasks other than data review until the Battelle report is completed. See "HED Reviewers Reassigned Because of 'Cut and Paste' Audit Results," Pesticide and Toxic Chemical News, pp. 15-16 (October 5, 1983).

decisions can be assured only if the underlying data and conclusions are subject to the same critical scientific process that applies to other scientific matters. . . . The opportunity for review by scientists outside the agency will provide a valuable additional incentive for [industry] to produce the best and most reliable data."<sup>24</sup>

Members of Congress and independent scientists have both stressed the importance of full disclosure and peer review of pesticide data in order to protect public health and the environment. As stated by Representative Schneider in opposing a bill that would have limited public disclosure of pesticide data, "[w]hen dealing with potentially hazardous chemicals, we must do everything in our power to facilitate peer review of testing methods, not set up roadblocks."25 The American Association for the Advancement of Science has urged Congress to retain full public disclosure, arguing that "[i]f independent scientific verification of [pesticide] data . . . is foreclosed . . . , both public and scientific accountability could be degraded unacceptably."26 Similarly, a group of over forty independent scientists has emphasized that, without public disclosure and peer review of pesticide data, "there is no way of knowing whether testing on these substances has been conducted thoroughly and the data honestly pre-

<sup>&</sup>lt;sup>24</sup>Kennedy Letter, supra note 7, at 842-43.

<sup>25128</sup> Cong. Rec. H5683 (daily ed. Aug. 11, 1982).

<sup>&</sup>lt;sup>26</sup>Letter from William D. Carey, Executive Officer, American Association for the Advancement of Science, to Representative Elliott H. Levitas (July 30, 1982), reprinted in 128 Cong. Rec. H5682 (daily ed. Aug. 11, 1982).

sented to the agencies charged with protecting the public's safety."27

In recognition of the importance of independent and public review of EPA's pesticide decision-making, Congress amended the pesticide laws in 1978 to provide for public disclosure of health and safety data. Douglas Costle, then-Administrator of EPA, testified in support of the 1978 public disclosure amendments that they properly recognize "the valuable contribution to Agency decision-making that can come from independent public review and comment upon the base of information on toxicity . . . and other characteristics of pesticides to which the public may be exposed."28 Senator Kennedy emphasized that public disclosure is of "particular significance" in light of EPA's prior failure to ensure that pesticides are supported by complete and accurate data.29 Public disclosure of pesticide data reflects Congress' recognition not only of the importance of peer review,30 but also of the "legitimate right of the public to know the basis for agency decisions."31

<sup>&</sup>lt;sup>27</sup>Letter to Members of Congress from Marvin S. Legator, Ph.D., and 46 other scientists (July 19, 1982), reprinted in 128 Cong. Rec. H5681-82 (daily ed. Aug. 11, 1982).

<sup>&</sup>lt;sup>28</sup>H. R. Rep. No. 663, 95th Cong., 1st Sess. 52 (1977).

<sup>29123</sup> Cong. Rec. 25711 (1977).

<sup>&</sup>lt;sup>30</sup>See, e.g., 128 Cong. Rec. H5679-80 (daily ed. Aug. 11, 1982) (Rep. Levitas); id. at H5683 (Rep. Schneider); id. at H5684 (Rep. Weaver); id. at H5687-88 (Rep. Gore); id. at H5689 (Rep. Scheuer).

<sup>&</sup>lt;sup>31</sup>H. R. Rep. No. 663, 95th Cong., 1st Sess. 18, 42 (1977). See also S. Rep. No. 334, 95th Cong., 1st Sess. 13 (1977); 123 Cong. Rec. 36008 (1977) (Rep. Fithian); 128 Cong. Rec. H5679 (daily ed. Aug. 11, 1982) (Rep. Levitas).

The 1978 amendments have allowed scientists and public interest groups, for the first time, to review the crucial health and safety data underlying the registrations of many widely used pesticides. The district court's decision, if upheld, would halt peer review in its tracks. Such a holding would create, once again, an anomalous situation in which pesticide health and safety data are excluded from the open peer review process used to ensure the integrity and objectivity of nearly all other scientific studies—even though, as recognized by Representative Scheuer, Chairman of one House Subcommittee with jurisdiction over pesticide research, "scientific peer review of pesticide research is absolutely necessary if the health and environment are to be protected." "12"

#### CONCLUSION

For the foregoing reasons, the decision of the district court should be reversed.

Respectfully submitted,

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<sup>32128</sup> Cong. Rec. H5689 (daily ed. Aug. 11, 1982).

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No. 83-196

CLERK

IN THE

# Supreme Court of the United States

OCTOBER TERM, 1983

WILLIAM D. RUCKELSHAUS, Administrator, United States Environmental Protection Agency Appellant,

vs.
Monsanto Company,

Appellee.

On Appeal From The United States District Court For The Eastern District of Missouri

BRIEF OF THE AMERICAN CHEMICAL SOCIETY,
THE AMERICAN INSTITUTE OF
CHEMICAL ENGINEERS,
THE AMERICAN INSTITUTE OF CHEMISTS,
AND THE WEED SCIENCE SOCIETY OF AMERICA
AS AMICI CURIAE IN SUPPORT OF APPELLEE

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# INDEX

			Page
Preliminary Statement			1
Interests of the Amici			2
Argui	ment		
I.	THE FORCED DISCLOSURE FOR AD- VERSE PRIVATE USE OF PESTICIDE TRADE SECRETS WILL CAUSE A REDUC- TION IN RESEARCH AND DEVELOPMENT IN THE APPLIED SCIENCES		
	<b>A</b> .	PRIOR DECISIONS OF THIS COURT HAVE EXPLICITLY RECOGNIZED THAT ELIMINATING PROPERTY RIGHTS AND PLACING INTELLECTUAL PROPERTY IN THE PUBLIC DOMAIN WILL RESULT IN DIMINISHED RESEARCH AND DE-	
		VELOPMENT	8
	B.	CHEMICAL INNOVATION IS IMPORTANT TO THE NATION	9
	C.	AMERICAN CHEMICAL PRODUCERS WILL BE DISADVANTAGED RELATIVE TO FOREIGN COMPETITION	11
	D.	PUBLIC DISCLOSURE OF TRADE SE- CRETS IS NOT NECESSARY TO ACHIEVE "PEER REVIEW"	12
II.	STI	E FIFTH AMENDMENT TO THE CON- TUTION PROHIBITS THE TAKING OF RET TECHNOLOGY LIKE OTHER	
	PKC	OPERTY	13
Concl	usion.	***************************************	14

# TABLE OF CITATIONS

	Page
CASES:	
Dawson Chemical Co. v. Rohm & Hass Co., 448 U.S. 176 (1980)	8,9
IBM v. Hitachi, No. 82 Civ. 4976 (N.D. Cal. 1982)	13
IBM v. Mitsubishi, No. 82 Civ. 0396 (N.D. Cal. 1982)	13
Kewanee Oil Co. v. Bicron Corp. 416 U.S. 470 (1974)	8
CONSTITUTIONAL PROVISIONS: U.S. Const. Amend. V	Passim
STATUTORY PROVISIONS:	
5 U.S.C. § 552(b)(4)	Passim
7 U.S.C. § 136 et. seq. (1982)	Passim
OTHER AUTHORITIES:	
V. Personick, The Job Outlook Through 1995: Industry & Employment Projections, Monthly Labor Review, U.S. Department of Labor, Bureau of	
Labor Statistics, Nov. 1983	13
Innovation and Private Investment in R&D, Chemical Engineering News, April 30, 1979	10,11

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#### PRELIMINARY STATEMENT

The American Chemical Society, The American Institute of Chemical Engineers, The American Institute of Chemists, and The Weed Science Institute of America submit this brief amici curiae in support of Appellee Monsanto Company. Both parties to this appeal have given said amici written consent to the filing of this brief. The original copies of said consents have been filed with the Clerk of this Court.

#### THE INTERESTS OF THE AMICI

The American Chemical Society (ACS) is incorporated by the United States Congress as a non-profit, membership, scientific, educational society composed of chemists and chemical engineers, and is exempt from the payment of federal income taxes under Section 501(c)(3) of the Internal Revenue Code of 1954, as amended.

As of December, 1983, the American Chemical Society consisted of more than 131,545 members. Its Federal Charter was granted in 1937 by an Act of the Congress. It replaced a New York State Charter, which had been effective since November 9, 1877.

Section 2 of the Act is as follows:

Sec. 2. That the objects of the incorporation shall be to encourage in the broadest and most liberal manner the advancement of chemistry in all its branches; the promotion of research in chemical science and industry; the improvement of the qualifications and usefulness of chemists through high standards of professional ethics, education, and attainments; the increase and diffusion of chemical knowledge; and by its meetings, professional contacts, reports, papers, discussions, and publications, to promote scientific interests and inquiry, thereby fostering public welfare and education, aiding the development of our country's industries, and adding to the material prosperity and happiness of our people."

The American Chemical Society is a leading publisher of scientific journals in all phases of chemistry and chemical engineering. The Society holds regular scientific meetings at which chemists with common interests have an opportunity to exchange scientific information and maintain contacts. Representatives of the Society have appeared by invitation before Congress and other government bodies to advise on the effect of proposed actions on science, science policy, and the contributions of science to the public welfare.

The American Chemical Society represents a cross section of the whole of chemistry as a science in the United States. The institutional support of the science of chemistry is found in colleges and universities, scientific research institutions, the chemical industry, and government agencies. All are interdependent in the scientific and societal sense, and they are broadly interdependent economically.

Of particular concern to the ACS is the negative effect that a reversal of the decision of the District Court below would have on research and development in all aspects of the chemical industry. It would disrupt the classical procedures by which scientists seek to derive benefit from their work: to publish or patent; or to keep in confidence. ACS submits that if developers of complex chemical processes may be stripped of constitutional protection for technology they choose to keep secret, then there exists a grave threat to chemical research and development as it exists in this country today. It is a matter of serious concern to the American Chemical Society that the incentive and support which traditional trade secret protection has brought to our nation's technological strength should not be unnecessarily diminished.

As applied particularly to the agricultural chemical industry, ACS is concerned that world food production may be adversely affected if pesticide research and development are unneccessarily impaired. American agriculture, which is an extremely important sector of our national economy, will suffer substantially if pesticide research is inhibited. Further, the pesticide industry produces a very favorable balance of trade which will be jeopardized by a diminution in the research incentives of American pesticide producers.

In the view of the ACS the decision of this Court in this case can have an effect on chemical research for the years to come, not only on research on pesticidal chemicals, but also on the growth of the chemical industry; on chemistry programs at universities; and on the employment of chemists; as well as on the ability of chemistry and chemists to contribute in an optimum way to the public welfare. The Society appreciates this opportunity to express and explain its concerns.

The American Institute of Chemical Engineers (AIChE) is a scientific and educational organization consisting of approximately 54,000 members, and is exempt from federal taxation under Section 501(c)(3) of the Internal Revenue Code. The majority of AIChE members are fully qualified professional chemical engineers, employed in industry, government at all levels, and in academia.

AIChE's objectives are to advance chemical engineering in theory and in practice, to maintain high professional standards among its members, and to serve society, particularly where chemical engineering can contribute to the public interest. AIChE shares the same concerns as the American Chemical Society as set forth above.

The American Institute of Chemists (AIC) is a nonprofit scientific and educational organization composed of more than 5,000 senior practitioners of the chemical sciences, and is exempt from federal taxation under section 501(c)(6) of the Internal Revenue Code. AIC members are found in positions of responsibility in universities, research institutions, government agencies and in the chemical industry. AIC shares the same concerns as the American Chemical Society as set forth above.

The Weed Science Society of America (WSSA) is a scientific and educational organization composed of 3,861 members, and is exempt from federal taxation under Section 501(c)(3) of the Internal Revenue Code. Approximately one-half of WSSA's members work in the academic and public research sectors of agricultural chemistry, while the remainder are employed in industry.

WSSA's objectives are to: encourage and promote the development of knowledge concerning weed science; publish the results of meritorious research and other information of value pertaining to weed science; promote unity in education, legislation, regulation, terminology, and other matters pertaining to weeds; foster high standards in weed control educa-

tion, and encourage its acceptance as a major field of training; promote ethical conduct and good fellowship among its members; aid in the coordination of activities and cooperate with member weed control organizations, and cooperate with other societies and organizations with similar and related interests; and remain a scientific and educational organization without the objective of financial gain. WSSA shares the same concerns as the American Chemical Society as set forth above.

## I. THE FORCED DISCLOSURE FOR ADVERSE PRI-VATE USE OF PESTICIDE TRADE SECRETS WILL CAUSE A REDUCTION IN RESEARCH AND DEVEL-OPMENT IN THE APPLIED SCIENCES.

As a federally chartered scientific and educational organization, the ACS is gravely concerned about the consequences a reversal in this case would have upon our nation's economy, as well as the adverse consequences which would be suffered by the Society's individual members engaged in agricultural research and development. All of your amici share these concerns.

Pesticide development is vital to American agriculture. The superior production capability of the American farmer is in large measure dependent upon the continued availability of effective new agricultural chemicals. Moreover, there is a constant need for new and more effective pesticides because of constant development of immunities by agriculture's natural enemies. Research and development, therefore, are critical in the pesticide field.

Your amici are convinced that a reversal in this case will foster an economic climate which will substantially diminish research and development of new pesticides. Chemists and other scientists working in all aspects of pesticide research will become unemployed as a consequence. Pesticide producers can not be expected to continue to invest millions of dollars on product research and development unless adequate benefits can be achieved by the investor.

It is well established that chemical producers must expend millions of dollars and conduct many years of research and development in order to create new pesticide products. As the court below stated:

A company's decision to develop pesticides requires it to make major commitments long before it can anticipate developing a commercial pesticide and even longer before it can expect any return on its investment. First, the company must synthesize, test and evaluate candidate pesticides typically for 4 to 8 years before it will identify a commercial candidate. It must then conduct extensive research for at least 6 additional years, including 2 years to obtain registration, before it can anticipate first marketing a product. Generally, a further 4 to 8 years will lapse before that product reaches a point where its costs of discovery, development and commercialization have been recovered. Second, the company must commit to the employment of a large scientific research group representing many disciplines, and to the acquisition of the necessary physical facilities and sophisticated equipment to conduct the intensive research required to assure some reasonable probability of success in discovering and commercializing a candidate pesticide. Third, any such company must usually commit to the expenditure of \$5 million to \$15 million annually for several years before it will develop a potential commercial pesticide candidate.

Jurisdictional Statement at 5a. Your amici are concerned that if the ability to protect secret technology is removed the American chemical industry will be unwilling to invest the vast funds and resources for research and development necessary to the creation of effective pesticides.

The 1982 Industry Profile Study of the National Agricultural Chemicals Association contains the most recent statistics concerning pesticide production, research and development. App. at la et. seq. Total pesticide research and development

expenditures were \$527 million in 1982. App. at 3a. Research on new products accounted for 66% of the total figure. The search for additional uses for existing products accounted for 25% of the expenditure and 9% was spent for registration under FIFRA and product defense. *Id.* Yet in 1982 only thirteen new compounds were registered with the EPA. Ten of those received conditional registrations, while three received full registration. *Id.* These data reflect that for every new compound registered in 1982, pesticide producers were investing more than \$26 million for new pesticide research.

In order to engage in innovative pesticide research, laboratories must be established and staffed with specialists to synthesize numerous compounds in an attempt to discover those which possess biological utility and commercial value. discovery phase consists of extensive laboratory tests on these potential insecticides, bactericides, nematocides, herbicides, fungicides and rodenticides. Laboratory tests must be followed by small plot tests and subsequently large scale field evaluations. The discovery phase is followed by the development phase, which consists of residue testing to determine, often to parts per billion, whether residues remain in food or feed crops, water or soil. Toxicology studies must be conducted in order to assure that the compound is not hazardous to man or the environment. These extensive studies on laboratory animals are required to determine proper precautions in the production, packaging, transportation, storage, use and disposal of the product. A petition for tolerances and registration is then assembled and filed for review with the EPA.

The entire process of pesticide discovery, development and registration has become increasingly expensive, time consuming and risky over the years. If the Appellant's position is upheld and all data filed with the EPA must be turned over to competitors of the developer, the risk equation is further overbalanced. The elimination of trade secret protection for pesticide developers can only serve to discourage further innovation.

A. PRIOR DECISIONS OF THIS COURT HAVE EX-PLICITLY RECOGNIZED THAT ELIMINATING PROPERTY RIGHTS AND PLACING IN-TELLECTUAL PROPERTY IN THE PUBLIC DO-MAIN WILL RESULT IN DIMINISHED RE-SEARCH AND DEVELOPMENT

In Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470 (1974), this Court held that federal patent law does not pre-empt state trade secret protections. In so ruling, this Court recognized that:

Trade secret law will encourage invention in areas where patent law does not reach, and will prompt the independent innovator to proceed with the discovery and exploitation of his invention. Competition is fostered, and the public is not deprived of the use of valuable, if not quite patentable information.

Id. at 485.

In Dawson Chemical Co. v. Rohm & Hass Co., 448 U.S. 176 (1980), this Court judicially recognized the importance of protecting the extraordinary investment of chemical manufacturers in the development of "new use" patents on chemical processes.

Development of new uses for existing chemicals is thus a major component of practical chemical research.

It is extraordinarily expensive. It may take years of unsuccessful testing before a chemical having a desired property is identified, and it may take several years of further testing before a proper and safe method for using that chemical is developed.

Under the construction of § 271(d) that petitioners advance, the rewards available to those willing to undergo the time, expense, and interim frustration of such practical research would provide at best a

dubious incentive. Others could await the results of the testing and then jump on the profit bandwagon by demanding licenses to sell the unpatented, nonstaple chemical used in the newly developed process.

As a result, noninventors would be almost assured of an opportunity to share in the spoils, even though they had contributed nothing to the discovery. The incentive to await the discoveries of others might well prove sweeter than the incentive to take the initiative oneself.

#### Id. at 221-22 (Emphasis added).

The analysis set forth above applies with equal force to both patent and trade secret protection. In both contexts, this Court has recognized the need for appropriate legal protections.

Your amici will not endeavor to improve upon Justice Blackmun's articulation of the importance of protecting chemical research, and the loss of incentive which will occur if the fruits of years of research are placed in the public domain. Your amici feel compelled to press their view that the confiscatory position taken by the EPA in this case will deter future scientific research in this country.

# B. CHEMICAL INNOVATION IS IMPORTANT TO THE NATION

Research on chemical pesticides and their uses has made countless contributions to our way of life. Notable have been contributions to human health and the production of food. In the field of agricultural chemicals which includes insecticides, herbicides, fungicides, nematocides, and plant growth regulators there have been remarkable advances. Only a decade ago insect pest control required the use of highly persistent chemicals at rates of 1 to 3 pounds per acre. Today new chemicals, of greatly improved environmental safety, control major crop insects at rates ranging from 0.2 pound per acre to as low as 0.01 pound per acre. Selective herbicides have

changed the nature of agricultural labor and costs. Even so, in many parts of the world major portions of crops are destroyed by pests before harvest, and more is lost while the harvest is in storage or transit. Much remains to be done, and there seems little doubt that safer and more effective chemicals can be found to help meet the needs of the hungry world population.

Innovation is absolutely critical in the pesticide industry. The biological targets of pesticides are dynamic. Their extremely rapid reproductive cycles and their inherent adaptability allow them to develop resistance and outright immunity to existing pesticides. As a result there exists a constant need to develop new and more effective chemicals to combat the natural enemies of world agriculture. Yet the costs of such development continue to escalate.

In 1978, the American Chemical Society analyzed recent trends in research and development, innovation, and productivity in the United States, and offered recommendations for enhancing the technological strength of the United States. <sup>1</sup> The statement described the innovative process and its underlying economics:

Industrial innovation is a complex process usually involving many steps and many factors. Generally the most common process starts with the discovery of a new fact or phenomenon resulting from a basic research program or occasionally from accidental observation. This is followed by an applied research program to find a use or an application of this discovery, or a completely unrelated research program to find a solution to an existing problem or Identification of a potential application is followed by a development process including, among other things, scale-up long-term testing, toxicity or safety evaluation, and market surveys. The final step is commercialization, which involves investment in a new plant, market development, and establishment of a distribution system.

<sup>&</sup>lt;sup>1</sup> Innovation and Private Investment in R&D, Chemical & Engineering News, April 30, 1979, at 36-44.

The driving force for the whole innovation process is the expectation of a satisfactory return on invested capital. If any factor in the process increases the overall cost or lengthens the time from the basic discovery to successful commercialization of a product, the return on investment will be decreased and the investment will appear to be less attractive. If investors even perceive at any stage in the innovation process that the return on investment will not be sufficient to justify the risk involved, no innovation will result....<sup>2</sup>

Future innovation is dependent upon the amount of investment capital which is generated by existing commercially successful products. In order for innovation to continue, it is essential that existing trade secrets be protected under the law.

#### C. AMERICAN CHEMICAL PRODUCERS WILL BE DISADVANTAGED RELATIVE TO FOREIGN COMPETITION

If the trade secret use and disclosure provisions of FIFRA are deemed to be constitutional by this Court, American chemistry and American chemists will be placed at a severe disadvantage relative to their foreign competitors. As the court below found:

The use or consideration for or disclosure to any third party by defendant of plaintiff's data will irreparably injure plaintiff in the conduct of its business and will confer an immediate and substantial competitive advantage upon its competitors, including foreign government-owned pesticide producers, by eliminating the significant leadtime advantages enjoyed by plaintiff, by advancing significantly the state of such competitors' technology and by permitting the registration of their products, both in the United States and foreign countries, without their incurring the enormous expenditure of time and money for research and development which plaintiff has incurred.

<sup>2</sup> Id. at 38.

Jurisdictional Statement at 25a.

Your amici feel strongly that the disclosure and use provisions of FIFRA will adversely affect our nation's technological strength. Foreign governments and industries enjoying the benefits of gratuitous trade secret information and possessing a great advantage in economic resources will reap substantial benefits at the expense of U.S. firms. The competitive advantage which foreign producers will gain thereby will result in lost opportunities and reduced employment in the chemical community in the United States.

#### D. PUBLIC DISCLOSURE OF TRADE SECRETS IS NOT NECESSARY TO ACHIEVE "PEER RE-VIEW"

The wholly speculative assertion made by Appellant that postdisclosure "peer review" of trade secret information will encourage research and enhance scientific progress is contrary to experience. Public interest environmental groups, the AFL-CIO and other amici supporting the Appellant do not conduct research. Peer review of scientific research is always done in private, prior to publication. Reviewers are fellow scientists, not competitors in the commercial market place. Peer review is an accepted scientific procedure, and the submission for publication of the work reviewed is at the discretion of the scientist-originator. The reviewer is not entitled to take the work of the originator as his own, for commercial gain in competition with the originator.

Moreover, the EPA Office of Pesticide Programs Hazard Evaluation Division (HED) performs exhaustive evaluations of test data. HED's four branches, toxicology, residue product chemistry, environment assessment and ecological effects, go far beyond "peer review" in performing their approval and acceptance function. Additionally, FIFRA § 25(d) authorizes the Scientific Advisory Panel to review the data requirements for registration and to conduct peer review in special cases when scientific advice is needed by EPA on pesticide issues. These reviews are conducted on a confidential basis with the recogni-

tion that the data under review are the property of the developer.

Your amici do not believe that public disclosure of trade secret complete test data will materially advance the scientific process, or contribute to the public welfare.

#### II. THE FIFTH AMENDMENT TO THE CON-STITUTION PROHIBITS THE TAKING OF SECRET TECHNOLOGY LIKE OTHER PROPERTY

In view of the vital importance of trade secret property in our technological society, your amici strongly urge this Court to uphold the rule that technological property is protected from confiscatory taking without just compensation under the Fifth Amendment to the United States Constitution.

There is clearly no social or economic utility in discouraging innovation. There is no redeeming public benefit in the provisions of FIFRA which are here at issue. Technological property is increasingly important to our national economy. Projections by the U.S. Department of Labor indicate that employment in high technology industries will increase faster than total employment between 1982-1995.<sup>3</sup> One need look no further than recent dramatic attempts at high technology industrial piracy to appreciate the value of trade secrets in the international economy. E.g., IBM v. Hitachi, No. 82 Civ. 4976 (N.D. Cal. 1982); IBM v. Mitsubishi, No. 82 Civ. 0396 (N.D. Cal. 1982) (disposition by consent decrees).

In view of the importance of trade secrets to our national economy in general, and to the chemical community in particular, your amici urge this Court to uphold the Appellee's position that trade secrets are constitutionally protected property under the Fifth Amendment.

<sup>&</sup>lt;sup>3</sup> V. Personik, The Job Outlook through 1995: Industry & Employment Projections, Monthly Labor Review, U.S. Department of Labor, Bureau of Labor Statistics (Nov. 1983), at 29. The B.L.S. has three different definitions of high-tech industries. "Under the broadest of the three definitions, high-tech industries account for 17 percent of all new jobs between 1982 and 1995; under the second definition, they account for 8 percent; while under the narrowest definition they represent slightly more than 3 percent." Id.

#### Conclusion

For the foregoing reasons, your amici urge this Court to affirm the judgment of the United States District Court for the Eastern District of Missouri.

Respectfully submitted,

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#### 1982

## INDUSTRY PROFILE SURVEY

## NATIONAL AGRICULTURAL CHEMICALS ASSOCIATION

Ernst & Whinney Washington, D.C.

### INTRODUCTION FOR THE 1982 NACA INDUSTRY PROFILE STUDY

(Prepared by Industry Statistics Committee)

The 1982 Industry Profile Study is the tenth survey to be conducted by the Industry Statistics Committee at the request of the Board of Directors. The data were collected for this study by Ernst and Whinney, who have collected the data on all of the ten studies.

Questionnaires were completed by 39 member companies which include 36 who conducted research and development.

### Sales Statistics (Schedules 1-4)

#### U.S. Pesticide Sales

Total U.S. pesticide sales (which includes U.S. sales of U.S. production and U.S. sales of non-U.S. production) were \$4.2 billion in 1982, down \$19 million or 0.5% compared to 1981. 1982 represented the first reduction in U.S. pesticide sales since the surveys were initiated ten years ago.

U.S. pesticide sales of U.S. production were \$3.6 billion or 88% of total U.S. pesticide sales and represented a decline of \$53 million or 1.4% from 1981.

U.S. pesticide sales of non-U.S. production increased by \$35 million or 7.3% in 1982 to \$510 million accounting for 12% of the total U.S. sales.

#### Herbicides

Total U.S. herbicide sales in 1982 were \$2.9 billion compared to \$2.8 billion in 1981, a 4% gain. Herbicide sales represented 69% (up 3%) of the total U.S. pesticide market in 1982.

#### Insecticides

Total U.S. insecticide sales were \$862 million in 1982, a reduction of \$142 million or 14% compared to 1981. U.S. insecticide sales account for 21% (down 3%) of total U.S. pesticide sales.

Non-U.S. Sales of U.S. Production

Non-U.S. sales of U.S. pesticide production were \$1.26 billion in 1982. This compares to \$1.25 billion in 1981, an increase of 1%. Non-U.S. Sales represented 26% of the total sales from U.S. production.

Research and Development Statistics (Schedules 5-9)

During 1982, 10 products received conditional registrations and 3 full registrations were reported.\* This compares with 10 conditional and nine full product registrations in 1981. Of the 36 reporting member companies which conducted research and development, 17 compounds were submitted for a full label in 1982 compared to 14 compounds which were submitted in 1981. (Schedule 5A, page 7)

Research and development expenditures were \$527 million in 1982, up \$75 million or 16.6% from the 1981 spending level.

Research on new products accounted for 66% of the \$527 million R&D expenditures. Product label expansion (uses on additional crops, additional weed or insect species, different application procedures, etc.) accounted for 25% of the expenditures. Reregistration and product defense accounted for the remaining 9%. (Schedule 6-A, page 9)

<sup>\*</sup> A registrant who satisfies all the data requirements of FIFRA receives a "full registration" for the product. If any of the data requirements are not fully satisfied, a "condition registration" may be issued, if the registrant agrees to develop and submit the required data, usually within a specified time period. A product that receives a full or conditional registration can be marketed by the registrant.

Over one-half of all R&D expenditures fell within the following three general categories: (Schedule 6-A, page 9)

Synthesis and Screening	
Field Plot Testing	19%
Process Development	13%

Herbicides accounted for 43% of all R&D expenditures, insecticides for 29% and fungicides 15%. These percentages were only slightly changed from 1981. (Schedule 6-A-1, page 13)

R&D expenditures as a percent of total U.S. sales and export sales for 1982 were 9.7%, up significantly from the 8.3% reported in 1981. (Schedule 7, page 17)

R&D costs, as a percent of sales, also vary considerably by size of company. In 1982 companies with sales under \$50 million had R&D costs that were 21% of sales, companies with sales of \$50-200 million had R&D costs that were 10% of sales and companies with sales exceeding \$200 million had R&D costs that were 9% of sales.

Cost of rebutting RPAR actions by EPA, which declined 30% in 1981, (Schedule 10-A, page 23) decreased another 12% in 1982 and now represents less than 1% of the total R&D expenditures.

### TABLE OF CONTENTS

	Schedule	Page
Letter of Transmittal		1
Important Survey Information		2
Pesticide Sales	1	3
U.S. Sales of U.S. Production of Pesticides	2	4
Non-U.S. Sales of U.S. Production of Pesti- cides	3	5
U.S. Sales of Non-U.S. Production of Pesticides	4	6
Research and Development Expenditures, Screening and Product Registration		
All Reporting Companies	5-A	7
Companies With 1982 Sales Volume Under \$50,000,000	5-B	8
Companies With 1982 Sales Volume \$50,000,000-\$200,000,000	5-B	8
Over \$200,000,000	5-B	8
Pesticide Research and Development Ex- penditures by Type and Reason		
All Reporting Companies	6-A	9
Companies With 1982 Sales Volume Under \$50,000,000	6-B	10
Companies With 1982 Sales Volume \$50,000,000-\$200,000,000	6-C	11
Companies With 1982 Sales Volume Over \$200,000,000	6-D	12
Research and Development Expenditures by Product Categories		
All Reporting Companies	6-A-1	13
Companies With 1982 Sales Volume Un- der \$50,000,000	6-B-1	14
Companies With 1982 Sales Volume \$50,000,000-\$200,000,000	6-C-1	15
Companies With 1982 Sales Volume Over \$200,000,000	6-D-1	16

	Schedule	Page
Relationship Between Pesticide Research and Development Expenditures and Total Sales by Sales Volume	7	17
Pesticide Research and Development Ex- penditures as a Percent of Sales		
All Reporting Companies	8	18
Companies With 1982 Sales Volume Under \$50,000,000	8	18
Companies With 1982 Sales Volume \$50,000,000-\$200,000,000	8	18
Over \$200,000,000	8	18
Personnel in Pesticide Research and Devel- opment		
All Reporting Companies	9-A	19
Companies With 1982 Sales Volume Under \$50,000,000	9-B	20
Companies With 1982 Sales Volume \$50,000,000-\$200,000,000	9-C	21
Over \$200,000,000	9-D	22
Cost Rebutting RPAR Actions by EPA		
All Reporting Companies	10	23
Payments to Cooperative Research and Development Programs		
All Reporting Companies	11	24

Ernst & Whinney

1225 Connecticut Avenue, N.W. Washington, D.C. 20036 202/862-6000

April 20, 1983

To Members of the National Agricultural Chemicals Association

The Industry Statistics Committee, acting on behalf of the Association, engaged us to compile the NACA Industry Profile Study for Years 1981 and 1982.

The data shown are derived from amounts reported to us by the participants. Source data used to compile the report have not been audited by us. The individual reports were reviewed for obvious clerical errors and missing data and, where necessary, we contacted the reporting companies on questionable data.

If you have any questions in regard to any of the composite information, do not hesitate to call Ms. Barbara Guyon at 202/862-6042.

Very truly yours,

Attachment

#### IMPORTANT SURVEY INFORMATION

The following points should be noted with respect to the NACA Industry Profile Survey.

- Questionnaires were sent to all members of NACA.
   We received responses from thirty-nine (39) companies, thirty-six (36) of which reported research and development information. All questions were not applicable to all companies; hence, certain areas of the report contain tabulated responses of less than 39 companies as appropriately indicated.
- Of the 42 companies that are considered Basic Producers, 36 responded to this survey.
- Sales data are arrayed in composite form only, in order to avoid disclosure of individual company data. Research and development information is shown in composite form, and segregated by sales volume.
- To avoid disclosure of individual company information, data were not shown (in which case a (D) appears) or were combined in some areas of the report. If less than three companies reported in any category or one company had more than 80 percent of the total in a category, the figures were not shown or were combined with another category.
- The source documents used to compile this report will be destroyed when their statistical use has been completed. No one other than Ernst & Whinney personnel assigned to this engagement had access to individual company documents.
- No attempt was made to investigate the possibility of duplicate reporting for the number of active ingredients (No. of AI) on Schedules 2, 3 and 4.

### PESTICIDE SALES

	1981	1982	Percent Change
	(000)	(000)	
U.S. Sales of U.S. Production	\$3,702,272	\$3,649,096	-1.4
Non-U.S. Sales of U.S. Production	1,251,323	1,262,514	+0.9
U.S. Sales of Non-U.S. Production	475,787	510,368	+7.3
Total Sales	\$5,429,382	\$5,421,978	-0.1

# SCHEDULE 2 U.S. SALES OF U.S. PRODUCTION OF PESTICIDES Composite Analysis of All Reporting Companies

	1981			1982			
	Proprietary	Non- Proprietary	Total	Proprietary	Non- Proprietary	Total	
Herbicides							
Sales Dollars (000)	1,910,340	576,438	2,486,778	1,982,238	558,377	2,540,615	
Pounds Al (000)	371,262	217,092	588,354	364,351	191,540	555,891	
No. of Al	. 54	38	92	60	41	101	
Insecticides							
Sales Dollars (000)	577,626	274,182	851,808	502,600	247,381	749,981	
Pounds Al (000)	77,832	103,281	181,113	55,767	81,822	137,589	
No. of Al	. 33	45	78	31	49	80	
Fungicides							
Sales Dollars (000)	171,025	31,376	202,401	152,381	33,792	186,173	
Pounds Al (000)	36,510	23,262	59,772	32,523	20,284	52,807	
No. of Al	. 18	31	49	18	36	54	
Plant Growth Regulators							
Sales Dollars (000)	. (D)	(D)	40,409	(D)	(D)	40,117	
Pounds Al (000)	. (D)	(D)	(D)	(D)	(D)	(D)	
No. of Al	. (D)	(D)	21	(D)	(D)	21	
Nematicides							
Sales Dollars (000)	. (D)	(D)	78,856	(D)	(D)	97,245	
Pounds Al (000)	. (D)	(D)	82,955	(D)	(D)	72,343	
No. of Al	. (D)	(D)	8	(D)	(D)	8	
Miscellaneous							
Sales Dollars (000)	. (D)	(D)	42,020	(D)	(D)	34,965	
Pounds Al (000)	(D)	(D)	(D)	(D)	(D)	(D)	
No. of Al	. (D)	(D)	30	(D)	(D)	31	
Total*							
Sales Dollars (000)	. 2,764,037	938,235	3,702,272	2,740,072	909,024	3,649,096	
Pounds Al (000)	. 514,249	423,688	937,937	477,131	359,070	836,20	
No. of Al	. 136	142	278	137	158	295	
No. of Companies	. 29	30	36	29	30	36	

<sup>(</sup>D) Not shown to avoid disclosure of individual company data.

Includes data not shown above due to disclosure.

### NON-U.S. SALES OF U.S. PRODUCTION OF PESTICIDES

		1981		1982			
	Proprietary	Non- Proprietary	Total	Proprietary	Non- Proprietary	Total	
Herbicides							
Sales Dollars (000)	430,304	159,311	589,615	373,697	216,251	589,948	
Pounds Al (000)	103,217	86,458	189,675	90,296	73,977	164,273	
No. of Al	48	27	75	46	26	72	
Insecticides							
Sales Dollars (000)	297,930	123,037	420,967	303,889	142,765	446,654	
Pounds Al (000)	39,229	58,883	98,112	30,090	62,107	101,197	
No. of Al	33	29	62	27	33	60	
Fungicides							
Sales Dollars (000)	206,607	6,315	212,922	170,907	21,911	192,818	
Pounds Al (000)	(D)	(D)	40,091	31,902	8,251	40,153	
No. of Al	18	13	31	17	13	30	
Plant Growth Regulators							
Sales Dollars (000)	(D)	(D)	16,945	(D)	(D)	18,085	
Pounds Al (000)	(D)	(D)	(D)	(D)	(D)	(D)	
No. of Al	(D)	(D)	19	(D)	(D)	19	
Nematicides							
Sales Dollars (000)	(D)	(D)	7,520	(D)	(D)	13,480	
Pounds Al (000)	(D)	(D)	(D)	(D)	(D)	(D)	
No. of Al	(D)	(D)	6	(D)	(D)	6	
Miscellaneous							
Sales Dollars (000)	3,354	0	3,354	691	838	1,529	
Pounds Al (000)	(D)	0	(D)	(D)	(D)	(D)	
No. of Al	10	0	10	5	4	9	
Total*							
Sales Dollars (000)	953,008	298,315	1,251,323	869,930	392,584	1,262,514	
Pounds Al (000)	180,476	159,087	339,563	164,608	155,446	320,054	
No. of Al	119	84	203	105	91	196	
No. of Companies	26	25	31	25	24	31	

<sup>(</sup>D) Not shown to avoid disclosure of individual company data.

<sup>\*</sup> Includes data not shown above due to disclosure.

### U.S. SALES OF NON-U.S. PRODUCTION OF PESTICIDES

	1981			1982		
	Proprietary	Non- Proprietary	Total	Proprietary	Non- Proprietary	Total
Herbicides						
Sales Dollars (000)	249,143	18,229	267,372	298,349	25,308	323,657
Pounds Al (000)	(D)	(D)	49,223	(D)	(D)	57,186
No. of Al	14	9	23	13	11	24
Insecticides						
Sales Dollars (000)	120,740	27,498	148,238	76,383	35,562	111,945
Pounds Al (000)	13,021	7,429	20,450	10,348	5,802	16,150
No. of Al	16	7	23	10	13	23
Fungicides						
Sales Dollars (000)	(D)	(D)	(D)	(D)	(D)	62,072
Pounds Al (000)	(D)	(D)	(D)	(D)	(D)	(D)
No. of Al	(D)	(D)	(D)	(D)	(D)	17
Plant Growth Regulators						
Sales Dollars (000)	0	(D)	(D)	0	(D)	(D)
Pounds Al (000)	0	(D)	(D)	0	(D)	(D)
No. of Al	0	(D)	(D)	0	(D)	(D)
Nematicides						
Sales Dollars (000)	0	(D)	(D)	0	(D)	(D)
Pounds Al (000)	0	(D)	(D)	0	(D)	(D)
No. of Al	0	(D)	(D)	0	(D)	(D)
Miscellaneous						
Sales Dollars (000)	(D)	0	(D)	(D)	0	(D)
Pounds Al (000)	(D)	0	(D)	(D)	0	(D)
No. of Al	(D)	0	(D)	(D)	0	(D)
Total*						
Sales Dollars (000)	418,810	56,977	475,787	428,500	81,868	510,368
Pounds Al (000)	64,657	21,024	85,681	61,830	32,916	94,746
No. of Al	45	24	69	38	31	69
No. of Companies	11	13	17	10	15	18

<sup>(</sup>D) Not shown to avoid disclosure of individual company data.

<sup>\*</sup> Includes data not shown above due to disclosure.

### **SCHEDULE 5-A**

### RESEARCH AND DEVELOPMENT EXPENDITURES, SCREENING AND PRODUCT REGISTRATION

		M	Ye	_	
		Number Reporting*	1981	1982	Percent Change
I.	Total R&D Expenditures	36	\$451,929,000	\$526,904,000	+ 16.6
11.	Total Compounds Screened	27	109,329	119,717	+ 9.5
111.	Number of New Products Regis- tered:				
	Tolerance Products:				
	Full Registration	6	7	2	
	Conditional Registration.	9	7	8	
	Non-Tolerance Products:				
	Full Registration	3	2	1	
	Conditional Registration.	4	3	2	
IV.	R&D Expenditures (excluding synthesis and screening) associ- ated with obtaining first full reg- istration		\$8,819,000**	\$ 15,045,000***	
V.	Number of Compounds submitted for first full registration:				1 1
	Tolerance Products	10	11	10	
	Non-Tolerance Products	7	3	7	

		Average Elapsed Time Per Produc				
		Full Registration			itional tration	
		1981	1982	1981	1982	
A.	Elapsed time from discovery to first full registration (months)	70	108	51	72	
B.	Elapsed time from first submission for temporary or experimental registration to commercial registration (months)	34	36	23	14	
C.	Elapsed time from submission to granting of commercial registration (months)	23	24	11	15	

<sup>\*</sup> Number of companies reporting in 1981 and 1982.

<sup>\*\*</sup> Expenditures for nine products receiving first full registration.

<sup>\*\*\*</sup> Expenditures for three products receiving first full registration.

### **SCHEDULE 5-B**

### RESEARCH AND DEVELOPMENT EXPENDITURES, SCREENING AND PRODUCT REGISTRATION

### Composite Analysis by Size of Company

	Number Reporting*	1981	1962	Percent Change
1982 Sales Volume Under \$50,000,000				
I. Total R&D Expenditures	17	\$45,569,000	\$45,189,000	-0.8
II. Total Compounds Screened	9	6,861	10,039	+46.3
III. Number of New Products Registered:				
Tolerence Products:				
Full Registration	2	5	0	
Conditional Registration	5	6	5	
Non-Tolerance Products:				
Full Registration	2	1	1	
Conditional Registration	1	2	0	
1982 Sales Volume \$50,000,000- \$200,000,000				
I. Total R&D Expenditures	8	\$81,866,000	\$101,629,000	+24.1
II. Total Compounds Screened	8	29,468	32,236	+9.4
III. Number of New Products Regis- tered:				
Tolerance Products:				
Full Registration	2	1	1	
Conditional Registration	2	1	1	
Non-Tolerance Products:				
Full Registration	0	0	0	
Conditional Registration	0	0	0	
1982 Sales Volume Over \$200,000,000				
I. Total R&D Expenditures	11	\$324,494,000	\$380,086,000	+17.1
II. Total Compounds Screened	10	73,000	77,442	+ 6.1
III. Number of New Products Regis- tered:		\		
Tolerance Products:				
Full Registration	2	1	1	
Conditional Registration	2	) 0	2	
Non-Tolerance Products:	-	1	-	
Full Registration	1	1	0	
Conditional Registration	3	i	2	

<sup>\*</sup> Number of companies reporting in 1981 and 1982.

### **SCHEDULE 6-A**

### PESTICIDE RESEARCH AND DEVELOPMENT EXPENDITURES BY TYPE AND REASON

### Composite Analysis of All Reporting Companies 1982

		Reason for I				
Type of Expenditure	New Product (\$000)	Product Expansion (\$000)	Reregis & Product (\$00	Defense	Total (\$000)	Percent of Total
Synthesis	52,253		3,879A		56,132	11
Screening						
Primary	26,868		2,583A		29,451	5
Secondary	36,736		3,538A		40,274	8
Subtotal	115,857	9,167		833	125,857	24
Field Plot Testing	47,354	47,095		3,669	98,118	19
Toxicology:						
Mammalian	25,859	10,083		9,340	45,282	9
Environmental/Wildlife	3,484	915		1,249	5,648	1
Metabolism	8,202	5,457		4,358	18,017	3
Environmental Chemistry	3,121	3,912		2,355	9,388	2
Residue Analysis	9,747	8,159		5,803	23,709	4
Formulation Development	17,875	14,129		2,564	34,568	6
Process Development	51,110	14,344		4,740	70,194	13
Registration	3,870	6,477		3,926	14,273	3
Administration/Support	21,860	8,562		2,687	33,109	6
Cooperative Expenditures	1,733	797		71	2,601	1
All Other Expenditures	36,269B	4,537		5,334	46,140	_9
Total	346,341	133,634		46,929	526,904	
Percent	66	25		9		100

Total 1981 R&D Expenditures: \$451,929,000

A-Combined to avoid disclosure of individual company data. B-Includes Other Basic Research Expenditures: \$20,897,000

#### **SCHEDULE 6-B**

### PESTICIDE RESEARCH AND DEVELOPMENT EXPENDITURES BY TYPE AND REASON

### Composite Analysis by Size of Company 1982 Sales Volume Under \$50,000,000

Reason for Expenditure

Type of Expenditure	New Product (5000)	Product Expansion (\$000)		Reregis- tration & Product Defense (5000)	Total (\$000)	Percent of Total
Synthesis	Not	e: Informati	ion in this	section	4,208	9
Screening:	is no	or shown to a	avoid discl	osure of		
Primary	indi	vidual comp	any data.		1,590	4
Secondary					1,313	3
Subtotal					7,111	16
Field Plot Testing	6,731	4,826		846	12,403	27
Toxicology:						
Mammalian	2,643	597		428	3,668	8
Environmental/Wildlife	460	85		238	783	2
Metabolism	630		71A		701	2
Environmental Chemistry	268	67		42	377	1
Residue Analysis	1,085	977		172	2,234	5
Formulation Development	1,654		1,285A		2,939	7
Process Development	1,385		636A		2,021	4
Registration	704	736		152	1,592	3
Administration/Support	4,942	2,030		743	7,715	17
Cooperative Expenditures	9,804A	,B,C	952A,	В	3,645A	. 8
All Other Expenditures						_
Total	30,306	11,874		3,009	45,189	
Percent	67	26		7		100

Total 1981 R&D Expenditures: \$45,569,000

A-Combined to avoid disclosure of individual company data.

B-Includes Subtotal for Synthesis and Screening.

C-Includes other Basic Research Expenditures.

#### SCHEDULE 6-C

#### PESTICIDE RESEARCH AND DEVELOPMENT EXPENDITURES BY TYPE AND REASON

### Composite Analysis by Size of Company 1982 Sales Volume \$50,000,000 - \$200,000,000

Reason for Expenditure New Product Reregistration Percent Product Expansion **Product Defense** Total of Type of Expenditure (\$000) (5000)(\$000)(\$000)Total Synthesis 8 8.472 Screening: Note: Information in this section Primary is not shown to avoid disclosure 3.334 3 Secondary of individual company data. 5,562 6 Subtotal 17,368 17 Field Plot Testing ..... 8,902 14,481 24,397 1.014 24 Toxicology: Mammalian..... 4.071 2,148 4,091 10 10,310 Environmental/Wildlife ...... 501 209 336 1.046 1 Metabolism ..... 1.125 1,583 668 3,376 3 Environmental Chemistry ...... 768 2 1.030A 1,798 Residue Analysis..... 2.547 2,786 1,213 6,546 6 Formulation Development...... 2,477 5 2.345A 4,822 Process Development ..... 9,460 1,967A 11,427 11 5 Registration..... 861 2,145 1,918 4.924 Administration/Support..... 3,163 2.952 537 7 6,652 Cooperative Expenditures ...... 0 2,080A,B 8.963A 9 All Other Expenditures..... 24,251B,C Total ..... 58,126 32,998 10,505 101,629 57 33 Percent..... 10 100

Total 1981 R&D Expenditures: \$81,866,000

A-Combined to avoid disclosure of individual company data.

B-Includes Subtotal for Synthesis and Screening.

C-Includes Other Basic Research Expenditures.

#### **SCHEDULE 6-D**

### PESTICIDE RESEARCH AND DEVELOPMENT EXPENDITURES BY TYPE AND REASON

### Composite Analysis by Size of Company 1982 Sales Volume Over \$200,000,000

Type of Expenditure	New Product (\$000)	Product Expansion (\$000)	Reregistration & Product Defense (\$000)	Total (\$000)	Percent of Total
Synthesis				43,452	11
Screening:	N	ote: Inform	nation in this section		
Primary	is	not shown	to avoid disclosure	24,527	7
Secondary	0	findividual	company data.	33,399	9
Subtotal				101,378	- 27
Field Plot Testing	31,721	27,788	1,809	61,318	16
Toxicology:		1- 1		1	
Mammalian	19,145	7,338	4,821	31,304	8
Environmental/Wildlife	2,523	621	675	3,819	1
Metabolism	6,447	3,829	3,664	13,940	4
Environmental Chemistry	2,085		5,128A	7,213	2
Residue Analysis	6,115	4,396	4,418	14,929	4
Formulation Development	13,744	10,619	2,444	26,807	7
Process Development	40,265	11,894	4,587	56,746	15
Registration	2,305	3,596	1,856	7,757	2
Administration/Support	13,755	3,580	1,407	18,742	5
Cooperative Expenditures  All Other Expenditures	119,804	A,B,C	17,707A,B	36,133A	9
Total	257,909	88,762	33,415	380,086	-
Percent	68	23	9		100

Total 1981 R&D Expenditures: \$324,494,000

A-Combined to avoid disclosure of individual company data.

B-Includes Subtotal for Synthesis and Screening.

C-Includes Other Basic Research Expenditures.

### **SCHEDULE 6-A-1**

### RESEARCH AND DEVELOPMENT EXPENDITURES BY PRODUCT CATEGORIES

### Composite Analysis of All Reporting Companies

### 1982

	Reason for Expenditure					
Product	New Product (\$000)	Product Expansion (\$000)	Reregis- tration & Product Defense (\$000)	Total (5000)	Percent of Total	Percent of Sales
Herbicides	140,227	66,432	22,461	229,120	43	4.2
Insecticides	99,069	38,935	12,187	150,191	29	2.8
Fungicides	53,741	18,427	7,028	79,196	15	1.5
Plant Growth Regulator,	35,438	3,062	1,608	40,108	8	0.7
Nematicides	5,490	2,678	1,775	9,943	2	0.2
Miscellaneous	12,376	4,100	1,870	18,346	_3	0.3
Total	346,341	133,634	46,929	526,904	100	9.7

### SCHEDULE 6-B-1

### RESEARCH AND DEVELOPMENT EXPENDITURES BY PRODUCT CATEGORIES

### Composite Analysis by Size of Company 1982 Sales Volume Under \$50,000,000

Reason fe	or Expen	diture
-----------	----------	--------

New Product (\$000)	Product Expansion (\$000)	Reregis- tration & Product Defense (\$000)	Total (\$000)	Percent of Total	Percent of Sales
A	A	A	11,670	26	5.5
16,053	3,717	1,063	20,833	46	9.9
3,284	2,694	854	6,832	15	3.2
A	A	A	2,851	6	1.4
A	A	A	122	0	0.1
10,969A	5,463A	1,092A	2,881	7	1.4
30,306	11,874	3,009	45,189	100	21.5
	A 16,053 3,284 A 10,969A	Product (\$000)  A A A 16,053 3,717 3,284 2,694 A A A 10,969A 5,463A	New Product   Expansion (\$000)   Expansion (\$000)	New Product (\$000)         Product Expansion (\$000)         Expansion (\$000)         Defense (\$000)         Total (\$000)           A         A         A 11,670           16,053         3,717         1,063         20,833           3,284         2,694         854         6,832           A         A         A         2,851           A         A         A         122           10,969A         5,463A         1,092A         2,881	New Product Product   Expansion (S000)   (S000

A-Combined to avoid disclosure of individual company data.

### **SCHEDULE 6-C-1**

### RESEARCH AND DEVELOPMENT EXPENDITURES BY PRODUCT CATEGORIES

### Composite Analysis by Size of Company 1982 Sales Volume \$50,000,000-\$200,000,000

Reason for Expenditure

Product	New Product (\$000)	Product Expansion (\$000)	Reregis- tration & Product Defense	Total (\$000)	Percent of Total	Percent of Sales
Herbicides	A	A	A	46,183	45	4.5
Insecticides	8,263	6,730	2,461	17,454	17	1.7
Fungicides	9,849	7,911	4,170	21,930	22	2.1
Plant Growth Regulators	A	A	A	6,120	6	0.6
Nematicides	2,341	0	0	2,341	2	0.2
Miscellaneous	37,673A	18,357A	3,874A	7,601	8	0.7
Total	58,126	32,998	10,505	101,629	100	9.8

A—Combined to avoid disclosure of individual company data. Number of Participants: 8

## SCHEDULE 6-D-1 RESEARCH AND DEVELOPMENT EXPENDITURES BY PRODUCT CATEGORIES

### Composite Analysis by Size of Company 1982 Sales Volume Over \$200,000,000

Reason for Expenditure

Product	New Product (\$000)	Product Expansion (\$000)	Reregis- tration & Product Defense (\$000)	Total (\$000)	Percent of Total	Percent of Sales
Herbicides	106,033	47,240	17,994	171,267	45	4.1
Insecticides	74,753	28,488	8,663	111,904	30	2.7
Fungicides	40,608	7,822	2,004	50,434	13	1.2
Plant Growth Regulators	A	A	A	31,137	8	0.7
Nematicides	A	A	A	7,480	2	0.2
Miscellaneous	36,515A	5,212A	4,754A	7,864	_2	0.2
Total	257,909	88,762	33,415	380,086	100	9.1

A—Combined to avoid disclosure of individual company data. Number of Participants: 11

### RELATIONSHIP BETWEEN PESTICIDE RESEARCH AND DEVELOPMENT EXPENDITURES AND TOTAL SALES BY SALES VOLUME

1981 SALES VOLUME					
Under \$50,000,000	\$50,000,000- \$209,000,000	Over \$200,000,000	All Companies		
20.4%	10.2%	7.4%	8.3%		
10.0%	8.8%	7.3%	8.9%		
17	7	12	36		
	20.4% 10.0%	Under \$50,000,000- \$50,000,000 \$209,000,000 20.4% 10.2% 10.0% 8.8%	Under \$50,000,000 \$000,000 \$200,000,000 \$200,000,000 \$200,000,000 \$7.4% \$10.0% \$8.8% \$7.3%		

	1982 SALES VOLUME					
	Under \$50,000,000	\$50,000,000- \$200,000,000	Over \$200,000,000	All Companies		
Total R&D as a Percent of Total Sales*	21.5%	9.9%	9.1%	9.7%		
Median Percent	14.7%	8.4%	10.3%	10.4%		
Number of Participants.	17	8	11	36		

<sup>\*</sup> Based on companies reporting both R&D and sales.



### PESTICIDE RESEARCH AND DEVELOPMENT **EXPENDITURES AS A PERCENT OF SALES**

	Percent of Total 1982 Sales*					
Type of Expenditure	Sales Under \$50,000,000	Sales \$50,000,000- \$200,000,000	Sales Over \$200,000,000	All Companies		
Total Synthesis and Screen-						
ing	3.4	1.7	2.4	2.3		
Field Plot Testing	5.9	2.4	1.5	1.8		
Toxicology						
Mammalian	1.7	1.0	0.7	0.8		
Environmental/ Wildlife	0.4	0.1	0.1	0.1		
Metabolism	0.3	0.3	0.3	0.3		
Environmental Chemistry	0.2	0.2	0.2	0.2		
Residue Analysis (Includes methods development)	1.1	0.6	0.4	0.4		
Formulation Development	1.4	0.5	0.6	0.6		
Process Development	1.0	1.1	1.4	1.3		
Registration	. 0.8	0.5	0.2	0.3		
Administration/Support	3.6	0.6	0.4	0.6		
Cooperative Expenditures				0.1		
	A 1.7	A 0.9	A 0.9			
All Other Expenditures (Includes Other Basin Re-						
search)	_	-	_	0.9		
TOTAL	21.5	9.9	9.1	9.7		
IVIAL	21.0	0.0	2.1	2.1		

\* Based on companies reporting both R&D and sales.

A-Combined to avoid disclosure of individual company data.

Number of Participants:

17

11

36

### **SCHEDULE 9-A**

### PERSONNEL IN PESTICIDE RESEARCH AND DEVELOPMENT

### Composite Analysis of all Reporting Companies

	Number o		
United States and International*	1981	1982	Percent Change
Level of Education			
Doctor's Degree	1,477	1,631	+10.4
Master's Degree	738	785	+ 6.4
Bachelor's Degree	1,249	1,374	+10.0
Other Training & Nontechnical	2,186	2,124	- 2.8
TOTAL U.S. & INTER- NATIONAL	5,650	5,914	+ 4.7

International personnel are those whose efforts are directed in support of domestic sales of pesticide products manufactured in the U.S. and in support of export sales of pesticides manufactured in the U.S.

#### -SCHEDULE 9-B

### PERSONNEL IN PESTICIDE RESEARCH AND DEVELOPMENT

Composite Analysis by Size of Company 1982 Sales Volume Under \$50,000,000

	Number of	Number of Employees		
United States and International*	1981	1982	Percent	
Level of Education				
Doctor's Degree	119	122	+2.5	
Master's Degree	112	112	0.0	
Bachelor's Degree	164	171	+4.3	
Other Training & Nontechnical	173	162	-6.4	
TOTAL U.S. & INTER- NATIONAL	568	567	-0.2	

International personnel are those whose efforts are directed in support of domestic sales of pesticide products manufactured in the U.S. and in support of export sales of pesticides manufactured in the U.S.

### **SCHEDULE 9-C**

### PERSONNEL IN PESTICIDE RESEARCH AND DEVELOPMENT

Composite Analysis by Size of Company 1982 Sales Volume \$50,000,000—\$200,000,000

	Number o	Employees	_
United States and International®	1981	1982	Percent Change
Level of Education			
Doctor's Degree	281	305	+ 8.5
Master's Degree	184	193	+ 4.9
Bachelor's Degree	292	307	+ 5.1
Other Training & Nontechnical	295	312	+ 5.8
TOTAL U.S. & INTER- NATIONAL	1,052	1,117	+ 6.2

International personnel are those whose efforts are directed in support of domestic sales of pesticide products manufactured in the U.S. and in support of export sales of pesticides manufactured in the U.S.

### **SCHEDULE 9-D**

### PERSONNEL IN PESTICIDE RESEARCH AND DEVELOPMENT

### Composite Analysis by Size of Company 1982 Sales Volume Over \$200,000,000

United States and International*	Number of Employees		
	1981	1982	Percent Change
Level of Education			
Doctor's Degree	1,077	1,204	+11.8
Master's Degree	442	480	+ 8.6
Bachelor's Degree	793	896	+13.0
Other Training & Nontechnical	1,718	1,650	- 4.0
TOTAL U.S. & INTER- NATIONAL	4,030	4,230	+ 5.0

International personnel are those whose efforts are directed in support of domestic sales of pesticide products manufactured in the U.S. and in support of export sales of pesticides manufactured in the U.S.

### COST OF REBUTTING RPAR ACTIONS BY EPA Composite Analysis of All Reporting Companies

	1981	1982	Percent Change
	(\$000)	(\$000)	
Research Develop- ment Expenditures	3,688	2,856	-22.6
Other Direct Costs	1,128	1,368	+21.3
TOTAL	4,816	4,224	-12.3

### PAYMENTS TO COOPERATIVE RESEARCH AND DEVELOPMENT PROGRAMS\*

### Composite Analysis of All Reporting Companies

	1981	1982	Percent Change
	(\$000)	(\$000)	
Lump Sum Payments	1,976	1,949	- 1.4
Other Costs	373	412	+10.5
TOTAL	2,349	2,361	+ 0.5

To develop or acquire data in response to EPA re-registration or data callin programs.

DEC 2 1983

No. 83-196

ALEXANDER L STEVAS.

#### IN THE

### Supreme Court of the United States

OCTOBER TERM, 1983

WILLIAM D. RUCKELSHAUS, ADMINISTRATOR,
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY,
Appellant,

MONSANTO COMPANY.

Appellee.

On Appeal from the United States District Court for the Eastern District of Missouri

BRIEF FOR THE

AMERICAN FEDERATION OF LABOR AND CONGRESS OF INDUSTRIAL ORGANIZATIONS (AFL-CIO), NATURAL RESOURCES DEFENSE COUNCIL, INC., ENVIRONMENTAL DEFENSE FUND, SIERRA CLUB.

FRIENDS OF THE EARTH,
CALIFORNIA AGRARIAN ACTION PROJECT,
NATIONAL COALITION AGAINST MISUSE
OF PESTICIDES, AND
NATIONAL AUDUBON SOCIETY
AS AMICI CURIAE IN SUPPORT OF APPELLANT

ALBERT H. MEYERHOFF 25 Kearny Street San Francisco, CA 94108

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### TABLE OF CONTENTS

	Page
INTRODUCTION AND STATEMENT OF THE INTEREST OF THE AMICI CURIE	1
SUMMARY OF ARGUMENT	7
ARGUMENT	9
I. AS A MEASURE ENACTED TO PROMOTE THE PUBLIC HEALTH AND SAFETY, § 10 OF FIFRA CLEARLY FURTHERS A "PUB-	
LIC USE" WITHIN THE MEANING OF THE FIFTH AMENDMENT	9
II. THE PURPOSE OF § 10 OF FIFRA IS TO PREVENT THE SALE OF PRODUCTS LIKE-LY TO HARM MEMBERS OF THE PUBLIC AND THAT PROVISION THEREFORE DOES NOT ON ITS FACE WORK AN UNCOMPENSATED TAKING	21
CONCLUSION	30
APPENDIX A	1a
APPENDIX B	3a
APPENDIX C	7a
APPENDIX D	20a

### TABLE OF AUTHORITIES

A	SES	Page
	AFL-CIO, et al. v. Gorsuch, Civ. Action No. 82-	
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	(D.N.J.)	14
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	234 (1964)	23
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	438 U.S. 59 (1978)	29
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	244 U.S. 100 (1917)	22
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	U.S. 394 (1921)	24
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		21
	(1968)	21
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	and Drug Administration, 704 F.2d 1280 (D.C.	
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TABLE OF AUTHORITIES—Continued	
	Page
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	12, 14
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5, 1977)	14
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mittee on Dept. Investigations, Oversight and	
Research (April 26-27, 1977)	13
tremaich (April 20-21, 1911)	10

TABLE OF AUTHORITIES—Continued	
	Page
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#### IN THE

### Supreme Court of the United States

OCTOBER TERM, 1983

No. 83-196

WILLIAM D. RUCHELSHAUS, ADMINISTRATOR,
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY,
Appellant,

MONSANTO COMPANY,

Appellee.

On Appeal from the United States District Court for the Eastern District of Missouri

#### BRIEF FOR THE

AMERICAN FEDERATION OF LABOR AND CONGRESS
OF INDUSTRIAL ORGANIZATIONS (AFL-CIO),
NATURAL RESOURCES DEFENSE COUNCIL, INC.,
ENVIRONMENTAL DEFENSE FUND,
SIERRA CLUB,

FRIENDS OF THE EARTH,
CALIFORNIA AGRARIAN ACTION PROJECT,
NATIONAL COALITION AGAINST MISUSE
OF PESTICIDES, AND
NATIONAL AUDUBON SOCIETY
AS AMICI CURIAE IN SUPPORT OF APPELLANT

This brief amici curiae is filed with the consent of the parties as provided for in Rule 36.2 of this Court's Rules.

### INTRODUCTION AND STATEMENT OF THE INTEREST OF THE AMICI CURIAE

Modern pesticide chemistry involves the synthesis of entirely new molecules of matter and their introduction

into the natural environment for the purpose of destroying harmful or unwanted plants, animals, fungi, or bacteria. See J.S. App., at 5a-7a. Because these chemicals are new, their effect upon beneficial plants, animals and the environment, as well as upon human beings, is initially unkown. Short-term, acutely toxic effects (ranging from skin irritations, dizziness, and nausea, to more severe poisoning, to death) are likely to be recognized relatively soon after synthesis; as a result, these hazards are often controlled through the handling or use directions for a new pesticide. But there is also the possibility of less obvious deleterious effects: "[T]hese toxic chemicals, used daily in our homes and on our farms, are suspected of having the potential for causing such tragic effects as cancer, birth defects, genetic mutations, and interference with biological reproduction." 123 Cong. Rec. 25712 (July 29, 1977) (remarks of Sen. Kennedy). Such effects have in some instances been discovered only after years of use of a particular chemical.1 The purpose of requiring health and safety testing of pesticides as a prerequisite to registration and sale is to avoid as far as

<sup>&</sup>lt;sup>1</sup> For example, in 1977 California removed the pesticide DBCP, which had been in use since the 1950's, from further use when a number of workers in a pesticide manufacturing plant were found to have become sterile. 3 Cal. Admin. Code § 6370. In 1979, the United States Environmental Protection Agency followed California's earlier decision and cancelled the registration of DBCP (44 Fed. Reg. 65135 (Nov. 1, 1979)), which, it now appears, is carcinogenic as well. See California Department of Health Services, Literature Review of Toxicological Aspects of DBCP and An Epidemilogical Comparison of Pattern of DBCP Drinking Water Contamination with Mortality Rates from Selected Cancers in Fresno County, California, 1970-79 (June 1, 1982) ("DBCP contamination of drinking water is associated with an increased number of deaths from 1970-79 from certain cancers associated with DBCP.") Only after DBCP was banned was the chemical discovered in over 2,000 drinking water wells in California, and in groundwater in Hawaii and Arizona as well. Ramlit Associates, Inc., Groundwater Contamination by Pesticides: A California Assessment, at 28 (submitted to California State Water Resources Control Board, June, 1983).

possible these after-the-fact discoveries that the pesticide injures people and the environment.

The amici curiae are a coalition of labor and environmental groups concerned with protecting their members from all avoidable health hazards resulting from the production and use of modern pesticides. The amici curiae's interest in this case stems from their efforts to obtain, under the Freedom of Information Act ("FOIA"), 5 U.S.C. § 552 et seq., and § 10(d) of the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), as amended in 1978, 7 U.S.C. § 136, the health and safety data the Environmental Protection Agency relied on in registering sixteen widely-used pesticides, including one (glyphosate or "Roundup") proposed for registration by appellee Monsanto Company.<sup>2</sup>

The reason the amici curiae are seeking this data has nothing to do with any commercial interest in pesticides, and the data these organizations are seeking does not concern chemical formulas, inert ingredients, or manufacturing processes. Indeed, there would be no reason for anyone—even a commercial competitor—to request information from EPA in order to discover the makeup of the active ingredient in a pesticide. The molecular formula of the active ingredient necessarily becomes known though the most basic principles of chemical nomenclature when a pesticide is marketed.<sup>3</sup> While information revealing

<sup>&</sup>lt;sup>2</sup> While the National Audubon Society did not join in that particular information request and has not therefore participated in the resulting litigation described at pp. 5-6, infra, the Audubon Society has made numerous similar requests and it is by reason of those requests that the Audubon Society joins in the filing of this brief amici curiae.

<sup>&</sup>lt;sup>3</sup> Under the system of chemical nomenclature, the scientific name of a substance specifies its formula. The system is "simple enough to allow any chemist familiar with the rules... to derive the structure of a given compound from its [chemical] name." T. Solomons, Organic Chemistry (1976), at 90-91. EPA regulations require that the scientific name of a pesticide's active ingredient appear on its label. 40 C.F.R. § 162.10(g) (1983). Consequently, the chemical makeup of the active ingredient in every pesticide marketed is com-

manufacturing processes for, or the identity or percentage of inert ingredients in, a pesticide is ordinarily not disclosed under FIFRA (7 U.S.C. § 136h(d)), an individual interested in obtaining this information would have little difficulty doing so, and therefore would have little incentive (even if it were possible to do so) to attempt to reason back from the data which is disclosable under FIFRA to discover these aspects of a pesticide's composition.<sup>4</sup>

The amici curiae do, however, have a critical reason for collecting pesticide health and safety data: to submit the data to independent scientists to obtain those scientists' judgment whether or not the tests performed indeed prove what the tests are alleged to have demonstrated—viz., that the pesticide in question, used in the

Second, as to the identity and proportional quantity of inert ingredients, these are "generally easily ascertainable through chemical analysis." McGarrity & Shapiro, The Trade Secrets Status of Health & Safety Testing Information: Reforming Agency Disclosure Policies, 93 Harv. L. Rev. 837, 876 (1980). The techniques available include chromotography and spectroscopy. See Maugh, "A Survey of Separative Techniques," 222 Science 259 (1983); Cooks, Busch & Glish, "Mass Spectrometry: Analytical Capabilities and Potentials," 222 Science 273 (1983); Wilkens, "Hyphenated Techniques for Analysis of Complex Organic Mixtures," 222 Science 291 (1983).

monly known within the field, and appears in generally available reference books. See, e.g., Farm Chemicals Magazine, 1982 Farm Chemicals Handbook, at C254. (A copy of the 1982 Farm Chemicals Handbook entry for Roundup appears as "Appendix A" to this brief.)

<sup>&</sup>lt;sup>4</sup> First, any chemist with knowledge of the major types of organic chemical reactions could develop a synthesis procedure for any specific pesticide compound. College organic chemistry students routinely develop such syntheses; one text, in fact, introduces students to the topic of chemical synthesis by presenting a method for deriving the synthesis procedure for 1,2 Dichloropropane, a major ingredient in the Shell pesticide D-D. See T. Solomon, Organic Chemistry, supra, pp. 53-55. Moreover, reference books are available which detail the manufacturing process for hundreds of pesticides. M. Sitting, Ed., Pesticide Manufacturing & Toxic Materials Control Encyclopedia (1980); M. Satriana, Ed., Insecticide Manufacturing—Recent Processes and Application (1983).

approved matter, "will not generally cause adverse effects on the environment," including adverse human health effects. FIFRA \$ 10(c)(5), 7 U.S.C. \$ 136a(c)(5).

The amici curiae's first FOIA request, in February, 1982, sought health and safety data, including "all documents relating to carcinogenicity, mutagenicity, neurotoxicity, and teratogenicity and other reproductive effects" of eleven named pesticides. The request was filed for the express purpose of "better protect[ing] the public and our members by ensuring that the health and safety tests . . . conducted by the chemical industry were adequate for that purpose." See Letter to Ann Gorsuch, February 2, 1982 (attached hereto as "Appendix B"). When the information votes not produced as required by statute, the amici curiae joined as co-plaintiffs in AFL-CIO et al. v. Gorsuch, U.S.D.C. D.C. No. 82-1195. As a result of a settlement of that suit, the amici curiae have obtained most of the data sought on ten of those chemicals and are currently in the process of assembling a panel of scientists to review that data and to prepare a report on the suitability of the test protocols used, and the adequacy and integrity of the data gathered, in order to assess the possible health risks.5 However, while many scientists have evidenced an interest in serving on such panels, the amici curiae's ability to proceed with the plans for scientific peer review of the AFL-CIO v.

The data that was requested and obtained consists largely of reports of the results of controlled experiments assessing the specific effects of exposure to a given pesticide on various animals. Excerpts from one typical study appear as "Appendix C" to this brief to aid the Court in understanding the nature of the materials at issue. See, for a detailed exposition of the types of studies that must be submitted to register various types of pesticides, 47 Fed. Reg. 53192 et seq. (Nov. 24, 1982) (proposed 40 C.F.R. Part 158); 40 C.F.R. Part 162 subpart A; EPA, Guidelines for Registering Pesticides in the United States (1981).

As part of the settlement of AFL-CIO v. Gorsuch, supra, the amici curiae agreed to certain limitations on disclosure of the data obtained. The excerpts contained in Appendix C conform to those limitations.

Gorsuch health and safety data has been impeded by the injunction in the present case. That injunction bars the release of the remaining data, including certain key studies on several pesticides and all of the data on one pesticide.

While AFL-CIO v. Gorsuch, supra, was pending, the amici curiae filed a second FOIA request for health and safety data, seeking information regarding five additional pesticides, including glyphosate ("Roundup"), a chemical produced by appellee. (A copy of this data request is attached to this brief as "Appendix D".) In February, 1983, EPA issued a final determination that would have allowed access to the Roundup health and safety data. However, the injunction in this case issued before the release of that data, or any of the other data pertaining

The vast majority of the 1,205 IBT health and safety studies supporting pesticide registrations have been found to be invalid due to wholesale fabrication of test data and fraudulent research. See EPA, The IBT Review Program: Study Matrix (May 10, 1983) ("IBT Study"). Three high-ranking IBT executives, including a former IBT employee subsequently employed by appellee Monsanto, have been convicted of fraud, including fabrication of data. United States v. Calandra et al., No. 81 C.R. 235 (N.D. Ill. 1980).

With regard to Roundup particularly, EPA has now found 23 of 37 IBT-supplied studies on Roundup to be invalid, including six of eleven IBT-supplied "pivotal" studies—viz., studies on carcinogenic, teratogenic, reproductive, and chronic feeding effects. Despite these deficiencies in the data supporting its registration, Roundup, like the other pesticides registered with the aid of IBT-supplied studies, remains on the market while replacement studies are being conducted. The amici curiae are interested both in examining the studies remaining after the elimination of the IBT data to determine whether those studies are adequate, standing alone, to indicate the safety to Roundup and, as well, to assess the replacement studies thus far supplied so as to avoid, through timely peer review, a repetition of the IBT debacle.

<sup>&</sup>lt;sup>6</sup> The amici curiae are particularly interested in reviewing the health and safety data for Roundup because of the extremely high proportion of Roundup studies supplied by Industrial Biotest Laboratories ("IBT") an independent testing organization widely used to conduct government-required health and safety tests.

to the pesticides included in that request. Thus, because of that injunction the *amici curiae* have been prevented from submitting to independent scientists for their evaluation the health and safety data on this second group of pesticides as well.

This brief is therefore directed at demonstrating that, as applied to encourage the disclosure of health and safety pesticide data to non-commercial entities such as the *amici curiae* for the purpose of scientific peer review, § 10 of FIFRA does not in any sense work an uncompensated taking violative of the Fifth Amendment.<sup>7</sup> This conclusion is, as we go on to show, sufficient to invalidate the injunction issued with respect to § 10 of FIFRA generally, under established law limiting successful facial challenges based on the Takings Clause to the rare statute that necessarily works an uncompensated taking on every conceivable application.

#### SUMMARY OF ARGUMENT

I. The District Court concluded, on the basis of the record in this particular case, that EPA could adequately protect the public health and safety by evaluating pesticide health and safety data in secret, without any public involvement. On this basis, that court determined that disclosure of pesticide health and safety data does not promote a "public use" and that § 10 of FIFRA, for that reason alone, is invalid under the Takings Clause of the Fifth Amendment.

As the legislative history of § 10 conclusively demonstrates, Congress' assessment of EPA's ability to unilaterally determine the harmful effects of pesticides was quite different from the District Court's assessment. Both in 1978, when the present form of § 10 was enacted, and in 1982, when Congress refused to pass amendments limiting disclosure of pesticide health and safety data, Congress had substantial reason to doubt the adequacy

<sup>&</sup>lt;sup>7</sup> This brief does not address the constitutionality of the data sharing provisions of § 3 of FIFRA, 7 U.S.C. § 136a, since those provisions in terms run in favor only of commercial competitors of a pesticide manufacturer.

of EPA review of pesticide health and safety data. Congress was aware that EPA regulation had failed in numerous instances to prevent pesticide poisoning and contamination. In addition, instances of data fabrication and misuse, undetected by EPA's review procedures, had begun to surface. By requiring the disclosure of pesticide health and safety data, Congress sought to enable independent scientists to review, both for basic integrity and for conceptual adequacy, the studies upon which the Agency had found the environmental and health effects of a particular pesticide not to be unreasonably detrimental. In addition, it was Congress' judgment that affected individuals should be able, with the assistance of organizations such as the amici curiae, to judge for themselves the safety of pesticides to which those individuals are exposed.

The disclosure provisions of § 10 are thus part of a well-considered scheme to protect the public and the environment from harm due to pesticide use. The District Court was not entitled to disregard, by a purported factual finding, or otherwise, Congress' conclusion as to the appropriate means of protecting against pesticide hazards. Thus, § 10 serves a "public use", as that term is used in Takings Clause jurisprudence, and the District Court's conclusion to the contrary cannot stand.

II. Identification of the public purpose underlying § 10 goes a long way toward demonstrating that disclosure of pesticide health and safety data to groups such as the amici curiae involves no compensable taking. While this Court has not settled upon any single test for separating a noncompensable economic regulation from a compensable taking, governmental regulation reasonably designed to prevent personal injury to individuals has long been understood to be at the core of the government's regulatory powers and therefore ordinarily not compensable. If there is any limit to this principle, it is in the rare circumstances, which certainly does not obtain here, in which the economic value of an owner's property interest is totally eliminated.

It is true that disclosure under § 10 is not limited to requests for health and safety data by noncommercial organizations committed to monitoring the hazards of pesticides. But the District Court did not purport to determine the likelihood and extent of the economic harm caused by the disclosure of any particular data regarding any specific pesticide to any distinct organization or individual. Except where it is clear that a statute regulating property denies all economically viable use of that property, such a facial invalidation of a statute under the Takings Clause is not proper. Hodel v. Virginia Surface Mining & Recl. Assn., 452 U.S. 264, 295-96 (1981). Further, under this Court's precedents, a Tucker Act, 28 U.S.C. § 1491, remedy would be available should such a taking actually occur, and for that reason as well, § 10 with its important role in protecting against pesticide injuries, may not be enjoined.

## ARGUMENT

I. AS A MEASURE ENACTED TO PROMOTE THE PUBLIC HEALTH AND SAFETY, § 10 OF FIFRA CLEARLY FURTHERS A "PUBLIC USE" WITHIN THE MEANING OF THE FIFTH AMENDMENT

As the District Court acknowledged, Congress enacted § 10 of FIFRA in 1978 as a health and safety measure central to the statute's regulatory scheme. J.S. App. 17a, 33a. Relying upon a legislative record containing numerous examples of EPA's failure to discover the chronic health effects of certain pesticides, Congress concluded that public review of the registration data would significantly reduce the likelihood that dangerous pesticides would be registered on the basis of false, incomplete or improperly analyzed data. The District Court, however, flatly rejected this congressional judgment. Instead, that court "found"—in direct conflict with the congressional findings and notwithstanding the extensive evidence before Congress that numerous pesticides registered by the EPA were causing cancer, sterility, genetic muta-

tions and birth defects—that EPA review was fully sufficient to protect the public from hazardous pesticides even if that review was made in total secrecy. On this basis the District Court held that the public disclosure provisions of § 10 do not further a "public use" within the meaning of the Fifth Amendment, and are therefore "beyond Congress' regulatory powers." J.S. App., at 33a.

The District Court's mode of analysis is utterly inconsistent with the permissible scope of judicial review of congressional action. As this Court's cases make clear, the District Court, rather than relying upon its own view of the "record facts," should have deferred to the congressional findings, which amply support the conclusion that § 10 serves perhaps the most essential "public use"—that of protecting the health and, indeed, the lives of million of Americans.

1. The legislative history of § 10 leaves no doubt that Congress was gravely concerned about the dangers of pesticide exposure, and with EPA's repeated failure either to discover, or to warn the public, that many commonly-used pesticides have the potential for causing cancer, birth defects, damage to the central nervous system, genetic mutations and interference with biological reproduction. This legislative history also makes plain that Congress believed public disclosure of pesticide registration data to be absolutely necessary if the public is to be adequately protected from hidden pesticide dangers.

Congress first became aware of the extent of the public danger resulting from EPA's maladministration of FIFRA from a series of governmental reports prepared

<sup>&</sup>lt;sup>8</sup> The District Court thus found that "[t]he EPA has the ability to obtain independent scientific review and evaluation of the information, research and test data submitted to it under FIFRA... without the necessity of public disclosure," J.S. App., at 24a (emphasis added), and concluded that "[t]he public interest in seeing that safe and effective products are marketed is satisfied by the EPA's painstaking analysis of the complicated data submitted by Monsanto to register its products," J.S. App., at 33a. See also J.S. App., at 22a.

by congressional subcommittees, the Government Accounting Office ("GAO"), and EPA itself. These reports unanimously concluded that the pesticide registration program had been quite ineffective, and that EPA had failed in numerous instances to detect serious hazards associated with exposure to particular pesticides. Each of the reports recommended public oversight of EPA's registration decisionmaking as an essential measure to protect the public from exposure to hazardous pesticides.

The leading report, prepared by the Senate Subcommittee on Administrative Practice and Procedure, flatly stated that "the pesticide registration program is in a state of chaos." Subcomm. on Admin. Practice and Procedure. Senate Judiciary Comm., The Environmental Protection Agency and the Regulation of Pesticides, 94th Cong., 2d Sess., at 23 (Comm. Print 1976). While this Report directed numerous specific criticisms at the Agency, its primary concerns were that the EPA had unwisely delegated the task of data review to inexperienced agency personnel, had "failed to . . . respond to early and repeated warnings that the data it was relying upon were faulty and incomplete," had "failed to consider previous critiques of safety testing data in its own files," and had "failed to take corrective action designed to discover and supplement faulty data." Id., at 19-20, 23, 25, 34. For these reasons, the Report concluded that "the American people cannot be reasonably assured that the Federal Government is protecting them from pesticides that pose a serious threat to their health" (id., at 23), and recommended public disclosure of pesticide registration data to permit public review and oversight of the pesticide registration program:

[S]crutiny of the data over and above what EPA can provide will sharpen the analyses and improve the regulatory effort. It might also provide some incentive for the companies to develop more accurate data and the EPA to improve the quality of its own internal reviews. [Id., at 49.]

A second report considered by Congress prior to the enactment of § 10 in its present form was prepared by EPA's Office of Pesticide Programs. See EPA Office of Pesticide Programs, FIFRA: Impact on the Industry, reprinted in S. Rep. No. 95-334, 95th Cong., 1st Sess. (July 6, 1977). This internal EPA Report acknowledged that "the Agency has, in fact, been negligent in its public duty," and also acknowledged that serious questions had been raised about the Agency's ability to adequately protect the public health and safety. Echoing the recommendation in the Senate Subcommittee Report, this EPA Report then urged Congress

[to permit] interested members of the public to examine the actual data which is submitted in support of the safety and efficacy of registered pesticides [in order] to encourage public understanding and criticism of Agency decision-making as well as to increase the knowledge of risks and benefits of pesticide use. [Id., at 41 (emphasis added).] °

Throughout Congress' consideration of the 1978 amendments, EPA reiterated its recommendation that pesticide health and safety data should be disclosed:

We believe that the right of public access to decision foundations is vitally important. Almost all our decisions concerning pesticides are based on the meaning of test data; public awareness of the complexity of these issues is critical to public acceptance of our risk/benefit approach. Public scrutiny and criticism can also improve the quality and thoroughness of our

<sup>\*</sup> See also Subcomm. on Oversight and Investigations of the House Comm. on Interstate and Foreign Commerce, "Cancer-Causing Chemicals in Food," 95th Cong., 2d Sess., at 18 (Comm. Print No. 95-67, December 1978) (concluding that "many pesticides which result in chemical residues in food and animal feed have never been tested for their potential to cause cancer, birth defects, and genetic mutations"); General Accounting Office, "Delays and Unresolved Issues Plague New Pesticide Protection Programs," at 19 (1980) (noting that "the public is exposed daily to many pesticides which are not supported by animal and environmental safety studies").

decision-making. [Hearings Before the House Agriculture Subcommittee on Departmental Investigations, Oversight and Research, at 148 (April 27, 1977) (statement of Douglas M. Costle) (emphasis added), quoted in S. Rep. No. 95-334, 95th Cong., 1st Sess., at 72 (July 6, 1977).]

See also Hearings Before the Senate Agricultural Subcommittee on Research and General Legislation, at 43-44
(June 9, 1977) (remarks of Douglas M. Costle). It was
therefore EPA's stated position—although the District
Court never took notice of the fact—that the Agency
could more effectively regulate the safety of pesticides if
the Agency did not "deny farmers or academicians or
any person who desires to interpret the wisdom of regulatory decisions the objective information which the Administrator has [used] to arrive at the subjective risk/
benefit balance called for in FIFRA." Id., at 619 (June
9, 1977 letter from Administrator Costle to Cong. Foley,
Chairman of the House Committee on Agriculture).

Accordingly, when the 1978 FIFRA amendments were debated, numerous Congressmen stressed the urgent need for public oversight of the pesticide registration program—both to ensure that industry data and methodology conformed to contemporary standards of scientific accuracy, and to provide the public with the basic information necessary to make the subjective determination whether the risk of exposure to a particular pesticide is unacceptably high. Sen. Kennedy, for example, speaking in support of the Senate bill, noted:

Of particular significance in the bill as reported is the provision for public disclosure of the safety testing data on pesticides submitted to the EPA by industry. While providing for sufficient protection of "trade secret" information relating to individual pesticide products, this provision will allow for public scrutiny of the EPA's regulatory effort. And I submit that the EPA needs all the help it can get in performing this very difficult regulatory task. [123 Cong. Rec. 25711 (July 29, 1977) (remarks of Sen. Kennedy) (emphasis added).]

Similarly, Cong. Fithian stated, in support of the comparable House bill:

The public has an inherent right to know about the potential damaging aspects or cancer-causing ingredients in all pesticides produced in this country and should be given the information about a pesticide's impact on man and his environment. [123 Cong. Rec. 36008 (Oct. 31, 1977) (remarks of Cong. Fithian).]

See also 157 Cong. Rec. 36006 (Oct. 31, 1977) (remarks of Cong. Spior); 123 Cong. Rec. 35999 (October 31, 1977) (remarks of Cong. Maguire); 123 Cong. Rec. 36011, October 31, 1977 (remarks of Cong. Moss). These expressions of concern, and this belief that public disclosure would promote the goal of protecting public health and safety, were reiterated in the pertinent House and Senate Reports. See, e.g., H. Rep. No. 95-663, 95th Cong., 1st Sess., at 18 (October 5, 1977) (referring to the Act's recognition of "the legitimate right of the public to know the basis for agency decision"); S. Rep. No. 95-334, 95th Cong., 1st Sess., at 13 (July 6, 1977) (noting that "[i]n areas dealing with potentially dangerous materials such as pesticides, . . . there is a substantial public interest in public disclosure of facts concerning their production and uses").

Despite Congress' enactment of present § 10 in 1978, its goal of encouraging independent scientific peer review and public oversight of EPA decisionmaking was long delayed. A series of lawsuits filed by pesticide manufacturers succeeded in enjoining the disclosure of any pesticide health and safety data for a period of years. Of Moreover, even after those injunctions were lifted, the EPA refused to produce data that was covered by § 10, and the amici curiae had to file a lawsuit, AFL-CIO v. Gorsuch, supra, to obtain such disclosure. Not

<sup>&</sup>lt;sup>10</sup> See, e.g., Union Carbide Agricultural Products Co. v. Costle, 632 F.2d 1014 (2d Cir. 1980), cert. denied, 450 U.S. 965 (1981) (reversing district court injunction); American Cynamid Co. v. Gorsuch, U.S.D.C. D.N.J. No. 77-226 (filed Feb. 3, 1977).

surprisingly, the public health crisis that had been the focus of congressional concern in 1978 considerably worsened during this period. And when Congress again addressed the public disclosure issue, in response to an unsuccessful industry-backed attempt to water down the public disclosure provision in 1982, the legislature expressed even more clearly the urgent public need for independent review of EPA decisionmaking. Indeed, Congress refused to restrict the public disclosure provisions enacted in 1978 largely because the legislature had become aware of even more compelling evidence—all apparently ignored by the District Court—that EPA was not fulfilling its statutory mandate to protect the public health and safety.

The 1982 debates contain powerful examples of EPA's utter failure to protect the public from exposure to hidden pesticide dangers. Cong. Heftel, for example, criticized the Agency's failure to notify the public of the danger of heptachlor exposure, noting that this pesticide

was used to spray pineapple crops [in Hawaii] and the public did not know that the remains, called pineapple chop, were being fed to dairy cows from which the people got their milk supply, which in turn was found to be contaminated at four times

<sup>11</sup> The unsuccessful 1982 amendments would have prohibited disclosure of all health and safety studies that involve "innovative" methodology or technology, a potentially crippling restriction. The House defeated this provision (see 128 Cong. Rec. H5690-93 (daily ed., Aug. 11, 1982), at the same time passing an amendment permitting private rights of action for injunctive relief under FIFRA (id.). These amendments were not acted on by the Senate and the result was retention of the 1978 law. An earlier industry-backed amendment, which would have permitted public access only to summaries of the health and safety data submitted to EPA by pesticide manufacturers, and which would have permitted public review of these summaries only in specified reading rooms, never even passed Committee. See generally Safir & Davis, Disclosure of Pesticide Safety Data: A Viable Compromise at Last?, 12 ELR 15017, 15022-24 (1982).

the maximum allowable level under the law, pertaining to heptachlor. 128 Cong. Rec. H5653 (daily ed., Aug. 11, 1982) (remarks of Cong. Heftel).]

The pesticide toxaphene was the focus of Cong. Yates' concern:

Toxaphene is a chemical that is used in Mississippi, Louisiana, in the Southern States as a spray for the growing of cotton. That in itself sounds entirely harmless; but it does not stay in place. What happens is that toxaphene, which is made up of a number of compounds, is very much like DDT in the respect that it has a very strong life. The toxaphene that is sprayed on crops in the Southern States is lifted by the winds and carried for distances of over 1,000 miles, to the city of Chicago. for one place, 1,000 miles away. Then it is dropped by rainfall onto the city of Chicago, it is dropped on all the communities surrounding the Great Lakes, and it is dropped into the Great Lakes themselves. . . . It is in the food chain that is being used by people all over the country. [128 Cong. Rec. H5670 (daily ed. Aug. 11, 1982) (remarks of Cong. Yates).]

Similarly, Cong. Carney complained of the agency's failure to warn the public of the dangers resulting from exposure to temik:

In 1970, a toxic pesticide produced by Union Carbide under the trade name Temik was first registered for crop use. It was reported in 1970 that soil residue data [submitted to EPA] indicated that this pesticide and its metabolites would rapidly decay and that movement of this chemical into the groundwater would not occur. In 1979, however, residents of my district were shocked to find their drinking water wells contaminated. Upon request, Union Carbide tested 10,000 wells, finding that 25 percent of those wells contained levels above the New York State guidelines. [128 Cong. Rec. H5691 (daily ed., Aug. 11, 1982) (remarks of Cong. Carney).]

These episodes of pesticide poisoning were brought to Congress' attention in 1982 to reemphasize the critical need for public disclosure and independent scientific review of pesticide registration data. This need was perhaps most clearly described by Cong. Gore, who used an example of PBB contamination to illustrate the importance of public disclosure of health and safety data:

We had this PBB tragedy in Michigan. . . . Before the mistake was discovered, hundreds of thousands of livestock were contaminated and consumers had ingested large amounts of products contaminated with PBB. Yet even after the mistake was discovered, farmers and consumers were faced with substantial fears and uncertainties because little information existed concerning the health effects of PBB and because test methods available for analyzing PBB's were limited, and little information was available about how extensively it could get into the environment. Now, if that tragedy had involved the accidental contamination of cattle feed with a pesticide instead of PBB and this provision [seeking to amend the public disclosure provisions of FIFRA applied, it would have significantly impaired the public's ability to obtain sound information concerning the potential risk posed by the pesticide. [128 Cong. Rec. H5688 (daily ed., Aug. 11, 1982) (remarks of Cong. Gore) (emphasis added).]

Cong. Gore was not the only Congressman to articulate the public purposes that would be served permitting public disclosure of pesticide health and safety registration data. Cong. Levitas, for example, who strongly opposed any limitation on the public's right to review such data, reminded his colleague that Congress had enacted § 10

to make available, for complete use and discussion on its validity and accuracy, information relating to the health and safety effects of products which... may have tremendous implications with respect to human health when introduced into the environment, into the food chain and into the bodies of individuals... [I] n order to ascertain where there have been flawed tests, where there have been inappro-

priate protocols runs or where there has been a failure to determine the environmental fate of a particular chemical, the public and scientific community need full access and open discussion of this information... Health and safety information should not be held to close to the chest as a proprietary matter, because you may find that something down the road can protect someone's life. [128 Cong. Rec., at H5679-80 (daily ed., Aug. 11, 1982) (remarks of Cong. Levitas) (emphasis added).]

Cong. Levitas also remarked that public disclosure was necessary to protect

the right of the people and the scientific community to have a full opportunity to assess, to discuss, to challenge, and to question the information that has been developed by a company and submitted to EPA to establish that their product is safe to use. We are talking about the right of the public and the scientific community to determine whether there are any flaws or defects or invalidity in the protocol... with respect to health and safety information. [128 Cong. Rec. H5679 (daily ed., Aug. 11, 1982) (remarks of Cong. Levitas) (emphasis added).] 12

Accord 128 Cong. Rec. H5668, H5683 (daily ed., Aug. 11, 1982) (remarks of Cong. Schneider); id., at H5683 (re-

<sup>&</sup>lt;sup>12</sup> In support of his position, Cong. Levitas entered into the Congressional Record a letter written by 41 distinguished scientists explaining why independent peer review is scientifically important. In part, that letter stated:

Act, there is no way of knowing whether testing on these substances has been conducted thoroughly and the data honestly presented to the regulating agencies charged with protecting the public's safety. That is the crucial issue, in our view. . . . It is no secret that some premarket testing in recent years has been conducted under less-than-rigorous standards, resulting in charges that testing was incomplete, inadequate, or the conclusions fraudulently reached. Premarket test data—the most crucial measure of a substance's potential effects on humans and the environment—must be available to the public. [128 Cong. Rec. H5681 (daily ed., Aug. 11, 1982) (emphasis added).]

marks of Cong. Hollenbeck); id. at H5689 (remarks of Cong. Scheuer).

3. As these excerpts from the legislative record make clear. Congress enacted § 10 to promote two related objectives.13 First, Congress believed that public disclosure, and independent scientific review, would minimize the risk that EPA's registration determinations would be based upon false, faulty or incomplete data or upon unsound or inadequate scientific methodology and analysis. Independent peer review is at the core of the scientific process because such review permits the hypotheses, data and conclusions of one scientist to be scrutinized, debated, replicated and corrected by the scientific community at large. Peer review also serves the prophylactic effect of inducing industry and the Agency to be more careful and more thorough in presenting their data and conclusions, knowing that these data and conclusions will later be subjected to rigorous scientific peer review. See Letter from FDA Commissioner Donald Kennedy to Senator Edward M. Kennedy (May 5, 1978), reprinted in Drug Regulation Reform of 1978: Hearings on S. 2755 Before the Subcomm, on Health and Scientific Research of the Senate Comm. on Human Resources, 95th Cong., 2d Sess., at 841-42 (1978).

Second, Congress believed that public disclosure would permit the millions of individuals in this country who are regularly exposed to pesticides—including workers in pesticide manufacturing plants, farmworkers and consumers—to decide for themselves whether the risks of long-term exposure to a particular pesticide, including such chronic health effects as cancer, sterility, genetic mutations or birth defects, are unacceptably high. Thus, even where EPA has decided that a particular pesticide will not cause "unreasonable adverse effects" to the environment within the meaning of 7 U.S.C. § 136a (c)

<sup>&</sup>lt;sup>13</sup> See also McGarrity and Shapiro, The Trade Secret Status of Health and Safety Testing Information: Reforming Agency Disclosure Policies, supra, 93 Harv. L. Rev., at 840-48.

(5) (D), Congress recognized that individual workers may nonetheless decide, if there is access to an independent scientific evaluation of the underlying data, that the risk of chronic health effects resulting from exposure to a particular pesticide is still unreasonably high, notwithstanding EPA's subjective judgment. On the basis of such a determination, such individuals could decide to change jobs, to change products, or to take other steps to reduce their exposure to a particular pesticide.

The District Court had no right to second-guess these legislative determinations. This Court has long held that the courts must defer to Congress when the legislature determines that a particular statutory program is likely to further the public health, safety, morals or general welfare, or otherwise to promote a "public use." This deference is perhaps best exemplified by Berman v. Parker, 348 U.S. 26 (1954), which rejected a challenge, on public use grounds, to the constitutionality of the District of Columbia Redevelopment Act. Plaintiffs in Berman were department store owners in southwest Washington who contended that Congress had no power to enact a redevelopment scheme that permitted their property to be sold to a private developer as part of the general District of Columbia Redevelopment Plan. Relying on long-established case law, the Court unanimously explained:

We deal . . . with what traditionally has been known as the police power. An attempt to define its reach or trace its outer limits is fruitless, for each case must turn on its own facts. The definition is essentially the product of legislative determinations addressed to the purposes of government, [and] when the legislature has spoken, the public interest has been declared in terms well-nigh conclusive. In such cases the legislature, not the judiciary, is the main guardian of the public needs to be served by social legislation. The role of the judiciary in determining whether that power is being exercised for a public purpose is an extremely narrow one. [348 U.S., at 32 (emphasis added).]

Where "Congress has declared the [statutory] purpose to be a public use, by implication if not by express words, . . . [i]ts decision is entitled to deference until it is shown to involve an impossibility." Old Dominion Co. v. United States, 269 U.S. 55, 66 (1925). As with other challenges to the legislature's efforts to accomodate the burdens and benefits of economic life, judicial inquiry into the legislative judgments underlying a statute like FIFRA "must be restricted to the issue whether [there exists] any state of facts either known or which could reasonably be assumed . . . [to] support [them]." United States v. Carolene Products Co., 304 U.S. 144, 154 (1938). As this Court stated in Firemen v. Chicago, R.I. & P.R. Co., 393 U.S. 129, 139 (1968) (emphasis added):

The District Court's responsibility for making "findings of fact" certainly does not authorize it to resolve conflicts in the evidence against the legislature's conclusion or even to reject the legislative judgment on the basis that, without convincing statistics in the record to support it, the legislative viewpoint constitutes nothing more than . . . "pure speculation."

Since § 10 is based on a "known . . . state, of facts" and Congress' "decision" on those facts does not "involve an impossibility," the District Court was required to defer to the congressional judgment that § 10 furthers a "public use."

- II. THE PURPOSE OF § 10 OF FIFRA IS TO PREVENT THE SALE OF PRODUCTS LIKELY TO HARM MEMBERS OF THE PUBLIC AND THAT PROVI-SION THEREFORE DOES NOT ON ITS FACE WORK AN UNCOMPENSATED TAKING
- 1. Ordinarily, establishing that the government has a legitimate public purpose is but a threshold inquiry in a Takings Clause case. Even where the government's goal is entirely permissible, the "Fifth Amendment's guarantee [is] designed to bar Government from forcing some people alone to bear public burdens which, in all fairness

and justice, should be borne by the public as a whole." Armstrong v. United States, 364 U.S. 70, 79 (1960). In this case, however, the governmental purposes underlying \$ 10 of FIFRA go a long way toward establishing that this case, like Penn Central Transportation Company v. City of New York, 438 U.S. 104 (1978), is not one in which the "economic injuries caused by public action [should] be compensated by the government." Id. at 124.14

Even if it is taken as agreed or established (J.S. App., at 30a-31a) that the required data constitutes a trade secret under the Restatement of Torts, that does not, as the District Court believed, simultaneously establish that the data constitutes property of the kind for which the government must provide compensation under the Takings Clause. The trade secret definition relied upon by the District Court (J.S. App., at 29a) appears in the Restatement of Torts, not of Property. A cause of action based on appropriation of a trade secret is based on breach of a confidential relationship or upon improperly obtaining the secret, and not simply upon disclosure of information a company would rather keep secret. See Restatement of Torts § 757; See also E.I. DuPont De Nemours Powder Co. v. Masland, 244 U.S. 100 (1917) (the "word property as applied to . . . trade secrets is an unanalyzed expression of certain secondary consequences of the primary fact that the law makes some rudimentary requirements of good faith. . . . The property may be denied but the [breach of] confidence cannot be"); Kewanee

<sup>14</sup> The analysis that follows assumes that appellee Monsanto retains a compensable property interest in its health and safety data even after submitting that data to the government to obtain the right to sell pesticides. We note, however, that this is at least a dubious proposition, even with respect to health and safety data filed with the government before the 1978 FIFRA amendments. (As to any data that may have been filed after 1978, the conclusion seems inescapable that Monsanto relinquished any interest the Company may have had in secrecy by submitting the data to EPA in the face of explicit statutory notice that the data would be disclosed to the public.) In fact, Monsanto's position with regard to post-1978 data is no different than that of a company applying for a patent on the express understanding that the quid pro quo for obtaining a seventeen-year monopoly is "refrain[ing] from keeping his invention a trade secret [by] disclos[ing] [the] process or data in sufficient detail to enable one skilled in the art to practice the invention once the . . . monopoly has expired." Universal Oil Products v. Globe Oil Refining Co., 322 U.S. 471 (1944).

For, where the purpose of a statute is, as here, to prevent tangible, physical injuries to people due to exposure to a particular product or property, this Court has had little difficulty, despite its inability otherwise to settle upon

Oil Co. v. Bicron Corp., 416 U.S. 470, 487 (role of trade secret protection is to prevent industrial espionage); see id., at 497 (Douglas, J., dissenting) ("[a] trade secret, unlike a patent, has no property dimension"). Indeed, "the term "trade secrets' has been defined both broadly and narrowly at common law, sometimes in ways which would encompass health and safety data and sometimes as limited to a 'plan appliance, formula, or process... used in... making, preparing, compounding, treating or processing articles." Public Citizen Health Research Group v. Food and Drug Administration, 704 F.2d 1280, 1286 (D.C. Cir. 1983) (quoting the construction of the Federal Trade Secrets Act, now 18 U.S.C. § 1905, in United States ex rel. Norwegian Nitrogen Products Co. v. United States Tariff Commission, 6 F.2d 491, 495 (D.C. Cir. 1925)).

Thus, it does not violate the Takings Clause for a state to alter or eliminate the protection accorded trade secrets under state law.

A person has no property right, no vested interest, in any rule of the common law . . . Indeed, the great office of statutes is to remedy defects in the common law as they are developed, and to adapt it to the changes of time and circumstance. [Munn v. Illinois, 94 U.S. 113, 134 (1877). See also Martinez v. California, 444 U.S. 277, 282 (1980).]

And any suggestion that the federal government has a lesser authority in this regard is belied by the Commerce Clause and by the Supremacy Clause. Such a proposition is particularly anomalous in light of the fact that it was conclusively established only in 1974 that state trade secret protection is valid despite the somewhat similar protections accorded by the federal patent laws. Kewanee Oil Co., supra. To concur in the District Court's view of the relationship between state trade secret protections and the Takings Clause would be to suppose that, had the decision in Kewanee Oil gone the other way, the federal government could be accused of "taking", in violation of the Fifth Amendment, every trade secret in the nation. Compare Compco Corp. v. Day Brite Lighting Co., 376 U.S. 234 (1964); Sears Roebuck & Co. v. Stiffel, 376 U.S. 225 (1964) (both holding, without indicating any Takings Clause problem, that a state cause of action for unfair competition by marketing an exact copy of a product neither patented nor copyrighted does interfere with federal patent and copyright policy and is therefore preempted).

a "set formula" for determining when a regulatory taking has occurred, in concluding that "justice and fairness are served by allowing any economic losses due to such regulation to fall upon the individuals whose activities are creating the risk of injury." Penn Central, supra, 438 U.S., at 124.

As long ago as 1887, the Court enunciated this core principle:

[All] property in this country as held under the implied obligation that the owner's use of it shall not be injurious to the community . . . . A prohibition . . . upon the use of property for purposes that are declared, by valid legislation, to be injurious to the health, morals or safety of the community, cannot, in any just sense, be deemed a taking or an appropriation of property for the public benefit. Such legislation does not disturb the owner in the control or use of his property for lawful purposes, nor restrict his right to dispose of it, but is only a declaration by the state that its use by anyone, for certain forbidden purposes, is prejudicial to the public interests. . . . The power . . . of prohibiting . . . such use by individuals of their property as will be prejudicial to the health . . . of the public, is notand, consistently with the existence and safety of organized society, cannot be-burdened with the condition that the state must compensate such individual owners for pecuniary losses they may sustain, by reason of their not being permitted . . . to inflict injury upon the community. [Mugler v. Kansas, 123 U.S. 623, 665, 668-69 (1887). See also, e.g., Erie R.R. v. Bd. of Public Utility Comm'rs, 254 U.S. 394, 410-11 (1921); Penn Central, supra at 145 (Rehnquist, J., dissenting). ]15

<sup>&</sup>lt;sup>15</sup> The majority opinion in *Penn Central* rejects the characterization of certain cases relied upon by the dissent as illustrative of the rule that harmful uses of property may be regulated without implicating Takings Clause considerations (438 U.S., at 134 n.30), and rejects as well the dissent's implication that only where the regulation is of injurious uses of property is the government entitled to rely on its police powers to deny compensation to those

Applying this principle, Congress could have determined that the frequency of after-the-fact discovery of pesticide-caused injuries justified banning all pesticides or severely limiting their use. Instead, Congress endeavored to separate out the safe from the unsafe pesticide by imposing upon those desiring to sell pesticides the responsibility for establishing their safety through extensive, costly prior testing.

Significantly, appellees do not challenge this requirement, despite its substantial economic costs, or claim that if the public insists on being certain that a particular pesticide is safe, the public must pay the cost of so demonstrating. In fact, any such claim would plainly be futile. Even before Mugler v. Kansas this Court recognized the validity of a statute imposing upon the owners of potentially dangerous properties the cost of establishing that those properties do not present a health hazard. In a case involving a statute requiring all ships entering the port of New Orleans to undergo a sanitary inspection at a quarantine station and to pay a fee to defray the costs of the inspection this Court stated:

If the law did not make this provision for assuming her freedom from infection, it would be compelled to enact more stringent and more expensive penalties against the vessel itself . . . The law now says that you must submit to this examination [and] . . . [f]or this examination and fumigation you must pay. The danger comes from you, and though it may turn out that in your case there is no danger,

economically affected. But neither Penn Central nor the law review article upon which the relevant portion of that opinion relies questions the vitality of Mugler v. Kansas as applied to true safety regulations, or of the principle Mugler announces. See Sax, Takings and the Police Power, 74 Yale L.J. 36, 48-50 (1964). See also Michelman, Property Utility and Fairness: Comments on the Ethical Foundations of 'Just Compensation' Law, 80 Harv. L. Rev. 1165, 1236 (1980) (a harm-prevention test under the Takings Clause has a "core of truth" even though it is sometimes difficult to distinguish situations in which the government is preventing a harm from those in which the government is promoting a benefit).

yet as you belong to a class from which all this kind of injury comes . . . [i]t seems to us that this is . . . a fair charge against the vessel. [Morgan v. Louisiana, 118 U.S. 455, 461-462 (1886) (emphasis in original).]

In FIFRA, Congress decided that the government should not conduct the health and safety testing itself but, intead, should require pesticide manufacturers to do so. while at the same time forbidding the manufacturers to keep secret the results of their tests. This disclosure requirement, as we have seen, has its own health justification, since, in Congress' view, adequate evaluation of the health and safety data requires public participation. No reason appears why the imposition of the lesser economic costs on pesticide manufacturers potentially resulting from this provision is compensable although much greater restrictions on the exploitation of property may be imposed, retroactively or prospectively, without compensation when the legislature, as here, is seeking to prevent an injurious use of property. Even if purported trade secrets are property for purposes of the Takings Clause, that property is not entitled to greater protection than other forms of property; consequently, it can no more be an uncompensated taking for Congress to require disclosure of health and safety data produced by pesticide manufacturers, on the ground that keeping that data secret entails dangers to the public health, than it is for Congress to regulate, on a similar basis, the purposes for which a particular pesticide may be sold.16

There is, it is true, at least one case in this Court which arguably involves regulation of a life-threatening use of property, and nonetheless holds that a compensa-

<sup>&</sup>lt;sup>16</sup> If further proof of the proposition that purported trade secrets are not entitled to greater protection from police power regulation than traditional forms of property is necessary, the venerable labelling cases provide the necessary proof. Savage v. Jones, 225 U.S. 501 (1912); Corn Products Refining Co. v. Eddy, 249 U.S. 427 (1918); National Fertilizer Assn. v. Bradley, 301 U.S. 178 (1937).

ble taking occurred. Pennsylvania Coal Co. v. Mahon, 260 U.S. 393 (1922); see id., at 417 (Brandeis, J., dissenting). Mahon may well have turned on a conclusion that no real dangers to people, as opposed to property, was at stake, or on the peculiar facts concerning the relationship between the plaintiff's and defendant's property rights of that case. But even if Mahon is read, instead, to establish a general Takings Clause rule for regulation of injurious or high-risk property, that case established only that when all economically viable use of distinct property is extinguished, retroactively, through regulation, there must be compensation. See Penn Central, supra, 438 U.S., at 127-28.

Plainly, this case does not come close to presenting such a limiting circumstance. Appellee Monsanto generated its health and safety data "primarily for registration purposes". J.S. App., at 21a. The data remains available to Monsanto for that primary purpose and, as well, for purposes such as protecting its workers, defending product liability lawsuits, and obtaining registrations in foreign countries. J.S. App., at 21a.<sup>17</sup> Thus, even if the economic value to Monsanto of its health and safety data is, as a whole, less now than before 1978, that value has certainly not been entirely, or even predominantly, extinguished, and *Mahon*, however construed, does not establish that a taking has occurred here.<sup>18</sup>

<sup>&</sup>lt;sup>17</sup> It is possible, of course, that because of disclosure Monsanto's data will be found faulty, and the registration of one or more pesticides will be withdrawn. But the possibility that the data generated for registration purposes does not satisfy the statutory health and safety requirements is a risk Monsanto assumed when the Company decided to invest in health and safety research to begin with, not a risk created by the disclosure requirements; and there can be no doubt that a proper registration refusal is not a compensable taking.

<sup>&</sup>lt;sup>18</sup> It should also be recognized that the economic loss about which Monsanto most loudly complains—viz., loss of the competitive advantage which exploitation of its health and safety data represents—is an advantage created in the first place largely by the FIFRA registration requirements. Absent those requirements, no

2. We recognize that § 10 does not limit disclosure to the type of health and safety data that the amici curiae have been seeking, nor are such groups the only kinds of organizations entitled to secure disclosure. For two separate reasons, however, the remote possibility that a particular disclosure request may eventually result in economic harm to appellee Monsanto cannot justify the broad injunction issued below, or even an injunction limiting the kinds of information that may be disclosed or the identity of permissible recipients.

In the first place, despite the voluminous record compiled in this case, the District Court did not focus upon the precise degree and kind of economic injury Monsanto is likely to suffer from any particular data disclosure request. Instead, that court held that there was "an immediate taking of Monsanto's property as of the passage of the amendments to FIFRA on September 30, 1978." J.S. App. at 36a. Thus, this case is structurally identical to Hodel v. Virginia Mining & Recl. Assn., 452 U.S. 264 (1981). In that case, although the trial court conducted a lengthy trial (id., at 274), there was no attempt to adjudicate any concrete controversy concerning the application of the Surface Mining Act "to particular surface mining operations or . . . [to] specific parcels of land." Id., at 295. This Court noted that because Takings Clause challenges often involve "essentially ad hoc, factual inquiries", such challenges must ordinarily "be conducted with respect to specific property, and the particular estimates of economic impact and ultimate valuation relevant in the unique circumstances."

major barrier to entry into the pesticide market would exist, and small companies able to afford basic development costs but not the very high costs of health and safety testing, would already be competing (albeit unsafely) with the large companies such as Monsanto. Furthermore, there is grave doubt concerning whether relative competitive disadvantage is compensable in any event under the Takings Clause, which ordinarily provides compensation only for the sale value of property, and not for collateral consequences of the loss of property. United States v. General Motors Corp., 323 U.S. 373, 378 (1945).

Id. Where, as in Hodel and here, there is no such specific focus, "the only issue properly before . . . this Court . . . is whether the 'mere enactment' of the . . . Act constitutes a taking." Id., quoting Agins v. Tiburon, 417 U.S. 255, 260 (1980). And, where that is the question, the statute may be voided only if it "denies an owner economically viable use of his [property]'." Id., at 296, quoting Agins, 417 U.S., at 260. Since, as we have already established (pp. 27-28 & ns. 17 & 18, supra) that is no more than the case here than it was in Hodel or Agins, the facial challenge must fail.

Further, even with respect to a particular disclosure request, an injunction prohibiting disclosure under the Takings Clause is inappropriate unless a registrant's cause of action for compensation from the United States under the Tucker Act, 28 U.S.C. § 1491, has been affirmatively withdrawn by FIFRA. Railroad Reorganization Act Cases, 419 U.S. 102, 127 (1974); Duke Power Co. v. Carolina Env. Study Group, 438 U.S. 59 (1978); Penn Central, supra, 438 U.S., at 94, n. 39. The District Court found the Tucker Act unavailable, holding that the compensation provisions of § 3 of FIFRA, 7 U.S.C. § 136a, were intended to be the sole source of compensation for any compensable injury due to the operation of either § 10 or § 3 of that Act. J.S. App. 35a. This conclusion cannot be squared with the approach of the Railroad Reorganization Act Cases even with respect to § 3. For the Railroad Reorganization Act Cases reject any inference, such as that drawn by the District Court in this case, that by providing some compensation scheme Congress signals an intent to withdraw the Tucker Act cause of action. With respect to § 10, moreover, the conclusion is even more untenable. FIFRA provides no compensation scheme for disclosure of registration data alone, as opposed to its use for registration purposes, nor does the compensation scheme in § 3 depend upon any disclosure under § 10 having occurred. Since FIFRA is entirely silent on the question of compensation for any economic injuries due to disclosure of such data, there is no basis for implying that Congress intended to forbid a cause of action for constitutional damages, if any, in the Court of Claims. For this reason as well, the total injunction issued below upon the disclosure Congress believed vital to assuring the public protection from pesticide injuries is improper.

### CONCLUSION

For the above stated reasons, the decision below should be reversed.

Respectfully submitted,

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Washington, D.C. 20006

<sup>\*</sup> With the assistance of Lawrie Mott. M.S.

# **APPENDICES**

## APPENDIX A

Roundup \*

CHEMICAL NAME: isopropylamine salt of Naphosphonomethyl) glycine.

COMMON NAME: glyphosate isopropylamine salt (ANSI, WSSA).

ACTION: Non-selective, postemergence herbicide.

TOXICITY: Acute oral LD<sub>50</sub>, 4300 mg kg (glyphosate). Isopropylamine salt, 4900 mg/kg (Roundup \* formulation).

SIGNAL WORD: WARNING.

APPLICATION: For control of many annual and perennial grasses and broadleaf weeds plus many tree and woody brush species in cropland and noncrop sites. A foliar-applied, translocated herbicide, it may be applied spring, summer, or fall to undesirable vegetation by boom equipment, hand-held and high volume equipment, and selective equipment such as recirculating sprayers, rollers, and wipers throughout the U.S. and, in some states, by aerial application equipment in forestry. Roundup \* is nonselective and may be applied to undesirable species in four ways in the culture of desirable species: (1.) Prior to the emergence of the following desirable species: alfalfa, edible beans, grasses for seed production, green or English peas, and turfgrasses. (2.) Prior to emergence or within (as a directed spray or spot treatment) a growing stand of the following desirable species: apples, asparagus, barley, citrus, cotton, corn, grapes, nut crops, cherries, oats, ornamentals. pears, sorghum (milo), soybeans, sugarcane, and wheat. (3.) Within established avocado groves. (4.) Through selective equipment in cotton or soybeans.

It may also be applied by conventional means or through selective equipment for general weed control in noncrop

areas such as industrial, recreational, and public areas such as airports, ditch banks, dry ditches and canals, fencerows, golf courses, highways, industrial plant sites, rights-of-way, etc., and in farmstead weed control.

FORMULATION: Roundup • is sold as an aqueous solution of the isopropylamine salt of glyphosate and wetting agents.

COMBINATIONS: Roundup \* may be tank mixed with Lasso \*, atrazine, and Princep \* for use in minimum tillage systems for corn and with Lasso \*, Lorox \*, Lexone \*, and Sencor \* for use in minimum tillage systems for soybeans.

## Glyphosate

BP: Monsanto Agricultural Products Co., a unit of Monsanto Co.

#### APPENDIX B

# NATURAL RESOURCES DEFENSE COUNCIL, INC.

25 Kearny Street San Francisco, California 94108 415 421-6521

Washington Office 725 I Street, N.W. Suite 600 Washington, D.C. 20006 202 223-8210 New York Office 122 East 42nd Street New York, N.Y. 10168 212 949-0049

February 2, 1982

VIA EXPRESS MAIL
RETURN RECEIPT REQUESTED

Anne Gorsuch, Administrator Environmental Protection Agency 401 M Street, S.W. Washington, D.C. 20460

FOI Officer A-101, Room 1132 401 M Street, S.W. Washington, D.C. 20460

# Dear Sir/Madam:

This is a request under the Freedom of Information Act (FOIA), as amended, (5 U.S.C. § 552) in conjunction with § 10(c) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) (7 U.S.C. § 136). It is made on behalf of the following organizations: American Federation of Labor and Congress of Industrial Organizations (AFL-CIO); Consumers Union of the United States, Inc.; Natural Resources Defense Council, Inc.; Environmental Defense Fund; The Sierra Club; Friends of the Earth; International Chemical Workers Union,

AFL-CIO; National Coalition Against Misuse of Pesticides; California Agrarian Action Project; and California Rural Legal Assistance.

On behalf of their members, these organizations request health and safety data retrievable from the files of the Environmental Protection Agency for the following pesticides: captan, toxaphene, ethylene debromide (EDB), dimethoate, temik, benomyl, carbon disulfide, carbon tetrachloride, TOK, lindane, and methyl bromide. In particular, we request all documents relating to carcinogenicity, mutagenicity, neurotoxicity, and teratogenicity and other reproductive effects of the above-named pesticides. In addition, we request copies of any reports provided by TRW Corporation concerning alternatives to 2, 4, 5-T. With regard to any studies that have been published on the above-mentioned pesticides, we request citations of the studies in lieu of the actual documents.

Under the Freedom of Information Act and FIFRA, we are entitled to all of the requested materials. While FOIA contains an exemption for certain matters that are trade secrets, Congress specifically provided in the 1978 amendments to FIFRA, that the materials being requested here are not trade secrets, and that members of the public have the right to obtain pesticide health and safety data on the acute and chronic effects from pesticide exposure.

However, if all or any part of this request is denied, we request, as the Act requires, a list of the specific statutory exemptions upon which the EPA is relying to withhold information. If the EPA determines that some portions of the requested material are exempt, we request, in accordance with the Act, that we be provided with the remaining non-exempt portions. We, of course, reserve the right to appeal any decision to withhold information and expect that you will list the address and office where such an appeal can be sent.

The requesting organizations are prepared, if necessary, to pay reasonable costs for locating and reproducing the requested documents. However, pursuant to amendments to the FOIA which provide for a reduction or waiver of fees if it is "in the public interest because furnishing the information can be considered as primarily benefiting the public," we request such a waiver of fees. The members and clients of the requesting organizations regularly are exposed to these pesticides, risking adverse health and safety effects. These documents are necessary in order to independently review the sufficiency of the tests performed on these chemical agents and thereby advise and protect our members concerning potential health risks, such as cancer, birth defects, and genetic mutations.

In addition, the health and safety properties of these pesticides is a matter of ongoing public debate. Release of this information will contribute to this debate by increasing public awareness of the possible adverse effects resulting from continued exposure to these toxic substances. Further, it is our intention, once this data is received, to have it reviewed by a body of independent scientists to determine whether the tests involved were adequately performed. Thus, disclosure of the data is required for the advancement of scientific research and to better protect the public and our members by ensuring that the health and safety tests here conducted by the chemical industry were adequate for that purpose. Finally, all of the organizations making this request are non-profit, will not benefit financially from this information, and seek to obtain it solely to promote the public interest and wellbeing.

If the Agency refuses to waive fees and if the costs exceed \$1,000, we request permission to review the records that are responsive to this request and then select those documents that we want copied.

As provided in the Freedom of Information Act, we expect the Agency's response within ten working days. If you need any further information regarding this request, please contact Al Meyerhoff by telephone at 415/421-6561.

Sincerly,

Al Meyerhoff Natural Resources Defense Council, Inc. Stephen P. Berzon Altshuler & Berzon

By /s/ Al Meyerhoff AL MEYERHOFF

AM:klw

bcc: Ralph Lightstone, CRLA David Roe, EDF Elizabeth Martin, CAAP

Nick Arguimbau/Steve Dreistad, CBE

Jackie Warren, NRDC, NY

Chuck Benbrook/Skip Stiles, Office of Cong. George Brown

Ken Finney, Governor Brown's Office

Erik Janson, FOE

Jay Feldman, NCAMP

Judy Kunofysky, Sierra Club, SF

Peter Weiner, Dept. of Industrial Relations, S.F.

Peggy Semenario, AFL-CIO Lawrie Mott, NRDC, SF

bcc: Laurence Gold, Special Counsel, AFL-CIO (Express Mailed) Harry Snyder, Consumers Union

#### APPENDIX C

Copies to: B. G. Julin (6) J. C. Summers (1)

A. M. Kaplan(1)

LONG-TERM FEEDING STUDY WITH 2-BENZIMIDAZOLECARBAMIC ACID, METHYL ESTER \* (MBC, INE-965) IN MICE

Medical Research Project No. 3207-001

Haskell Laboratory Report No. 70-82

Part I of II Parts

Final Report on a Study Conducted 10/13/78-10/16/80

Report by: /s/ Craig K. Wood
CRAIG K. Wood
Section Supervisor
Chronic Oral Investigations

Approved by /s/ Phillip W. Schneider, Jr.
PHILLIP W. SCHNEIDER, JR.
Study Director
Section Supervisor,
Chronic Inhalation Investigations

/s/ Henry J. Trochimowicz HENRY J. TROCHIMOWICZ Manager, Toxicology

<sup>\* 9</sup>th CAS: Carbamic Acid, 1H-Benzimadazol-2-yl-, methyl ester

Reviewed by: /s/ Christiann M. Barba CHRISTIANN M. BARBA Auditor, Quality Assurance Committee

CKW:jrg:WP:2.2

Date Issued: January 26, 1982

N.B. References: E-18685; E-18685-AA, -AB, -AC, -BA,

-DA, -DB, -EA, -EB

This report contains 886 pages

## DUPONT [LOGO]

## HASKELL LABORATORY

## TABLE OF CONTENTS

	Page
Acknowledgments	6
Summary	8
Introduction	10
Study Objective	12
Sponsor and Test Facility	13
Test Material	13
Procedure	13
Statistical Analysis	19
Results	
A. Mean Body Weights and Weight Gains	20
B. Mean Daily Diet Consumption, Food Efficiency and Intake of MBC	20
C. Clinical Observations and Survival	22
D. Hematological Measurements	25
E. Pathological Findings	
1. Organ Weights/Final Body Weights	26
2. Histomorphological Changes	27
Discussion	30
Appendix A-Protocol with Amendments and Ad-	
denda	62
Appendix B—Dietary Analyses	87
Appendix C-Individual Body Weights	103
Appendix D—Individual Clinical Observations	199
Appendix E-Final Clinical Pathology Report	209
Appendix F-Individual Organ and Body Weights	268
Appendix G-Final Pathology Report	285

## DUPONT [LOGO]

## HASKELL LABORATORY

## TABLES

		Page
I.	Two-Year Feeding Study in CDR-1 Mice with MBC; Male Mean Body Weights	33
II.	Two-Year Feeding Study in CDR-1 Mice with MBC; Male Mean Body Weight Gains	35
III.	Two-Year Feeding Study in CDR-1 Mice with MBC; Female Mean Body Weights	37
IV.	Two-Year Feeding Study in CDR-1 Mice with MBC; Female Mean Body Weight Gains	39
v.	Two-Year Feeding Study in CDR-1 Mice with MBC; Male Mean Daily Diet Consumption	41
VI.	Two-Year Feeding Study in CDR-1 Mice with MBC; Male Mean Food Efficiency	43
VII.	Two-Year Feeding Study in CDR-1 Mice with MBC; Female Mean Daily Diet Consumption	45
VIII.	Two-Year Feeding Study in CDR-1 Mice with MBC; Female Mean Food Efficiency	47
IX.	Two-Year Feeding Study in CDR-1 Mice with MBC; Male Mean Daily Intake of MBC	49
X.	Two-Year Feeding Study in CDR-1 Mice with MBC; Female Mean Daily Intake of MBC	51
XI.	Clinical Signs Observed in Male and Female Mice in MR-3207	53
XII.	Mean Organ and Body Weights of Male Mice Fed Diets that Contained 0, 500, 1500, or 7500-3750 ppm MBC (Final Sacrifice)	54
XIII.	Mean Relative Organ Weights of Male Mice Fed Diets that Contained 0, 50, 1500, or 7500-3750 ppm MBC (Final Sacrifice)	55

#### 11a

# DUPONT [LOGO] HASKELL LABORATORY

## TABLES-Continued

		Page
XIV.	Mean Organ and Body Weights of Female Mice Fed Diets that Contained 0, 500, 1500, or 7500 ppm MBC (Final Sacrifice)	56
XV.	Mean Relative Organ Weights of Female Mice Fed Diets that Contained 0, 500, 1500, or 7500 ppm MBC (Final Sacrifice)	57

## 12a

# DUPONT [LOGO] HASKELL LABORATORY

## FIGURES

		Page
1.	Growth Curve of Male Mice in MR-3207	58
2.	Growth Curve of Female Mice in MR-3207	59
3.	Survival of Male Mice in MR-3207	60
4.	Survival of Female Mice in MR-3207	61

# DUPONT [LOGO] HASKELL LABORATORY

#### CONFIDENTIAL

### LONG-TERM FEEDING STUDY WITH 2-BENZIMIDAZOLECARBAMIC ACID, METHYL ESTER (MBC, INE-965) IN MICE

Medical Research Project No. 3207-001

Haskell Laboratory Report No. 70-82

Summary

Male and female CDR-1 mice were fed for two years with diets that contained 0, 500, 1,500 or 7,500 ppm MBC. Due to a high mortality rate among male mice in the 7,500 ppm MBC treatment group, the dietary concentration of MBC for this male group was reduced to 3,750 ppm during test week 66 and, finally, the group was terminated during test week 73.

No effect on body weight, weight gain, clinical observations, or hematological parameters that could be attributed to the dietary administration of MBC was observed.

Male mice in the 7,500-3,750 ppm MBC group tended to consume more diet and had a lower food efficiency than male mice in the control group. Survival of male mice in the 1,500 and 7,500-3,750 ppm groups was significantly lower than that of the male control mice. Survival among male mice in the test groups was found to be related to the dietary concentration of MBC.

Male mice in the 1,500 and 7,500-3750 ppm MBC groups and female mice in the 7,500 ppm MBC group exhibited compound-related histomorphological changes in the kidney. Degenerative or toxic changes were observed in the livers of male mice in the test groups.

MBC administration in the diets of male and female mice, under the conditions of this study, resulted in a hepatic carcinogenic effect. No "no observable effect level" of MBC was observed for this effect. No carcinogenic effect was observed in any other organ system examined.

# DUPONT [LOGO] HASKELL LABORATORY

## LONG-TERM FEEDING STUDY WITH 2-BENZIMIDAZOLECARBAMIC ACID, METHYL ESTER (MBC, INE-965) IN MICE

Medical Research Project No. 3207-001

Haskell Laboratory Report No. 70-82

#### Introduction

2-Benzimidazolecarbamic acid, methyl ester (MBC; INE-965) is considered to be a metabolite of 1-butylcarbamoyl-2-benzimidazolecarbamic acid, methyl ester (Benlate<sup>R</sup>. Benomyl, INT-1991). It is considered to have very low acute toxicity by the oral route of administration with an approximate lethal dose in young adult male CDR rats of greater than 17,000 mg MBC/kg body weight. However, single doses of 1,000 mg MBC/kg body weight or greater were associated with histologic and/or gross abnormalities in the testes. These abnormalities, which consisted of small, soft and/or discolored testes associated with degenerative germinal epithelium and a reduction in or the absence of sperm, were also observed in young male CDR rats that received ten, 3,400 mg/kg body weight doses of MBC over a two-week period. Other MBC-related effects noted after repetitive oral administration of 3,400 mg MBC/kg body weight included edema and focal necrosis of the duodenum, reduction in the blood-forming elements of the bone marrow, and a decrease in the large globular-shaped vacuoles located centrilobularly in the liver of the rats that survived the treatment. Two of the six treated rats died before the tenth treatment.

TABLE I

### 2-YEAR FEEDING STUDY IN CDR1 MICE WITH MBC

#### MALE

### MEAN BODY WEIGHT (g)

		ODI WEIG		VII
Group:	I	III	v	7500-
	Control	500 PPM	1500 PPM	3750 PPM
Time on Test Weeks				
0	27.6	27.6	27.6	27.6
1	29.5	29.4	29.7	29.0
2	31.4	31.0	31.2	31.1
3	32.7	31.9*	31.8*	31.4*
4	33.2	32.9	32.7	32.6
5	34.3	34.1	34.1	33.6
6+	35.1	34.9	34.7	34.4
7	35.6	35.0	35.5	34.9
8	36.1	35.8	35.9	35.7
9	36.0	36.3	36.8	36.0
10	37.4	36.1	37.0	36.3
11	36.4	35.7	35.8	34.2*
12	36.9	36.4	36.8	36.0
13	37.1	36.6	37.2	36.1
14	38.0	37.7	38.0	37.0
15	35.4	36.2	37.0*	34.6
16	37.8	38.0	38.8	37.7
17	38.2	38.4	38.4	37.8
18	39.1	39.2	38.7	38.4
19	39.5	39.2	39.5	38.9
20	40.3	39.7	39.4	39.8
21	39.6	39.1	39.4	38.6
22	40.5	40.3	39.9	39.1
23	41.2	40.4	40.5	40.1
24	41.1	40.8	40.8	40.3
25	41.2	40.5	40.5	40.0
25+	41.9	41.2	41.2	41.3

<sup>\*</sup> Different from control at P < .05 level of significance.

17a

## TABLE I-Continued

Group:	I	III	v	VII 7500-
	Control	500 PPM	1500 PPM	3750 PPM
Time on Test Weeks		0001111	10001111	01001111
28	42.4	41.9	42.1	41.4
30	43.6	42.8	42.7	42.1
32	44.2	42.5	42.4	42.4
34	40.8	40.2	40.2	40.8
36	43.4	41.7	42.0	42.1
38	43.0	41.6	41.7	41.2
40	42.6	42.1	42.4	41.9
42	42.3	41.6	40.9	40.8
44	43.5	42.5	42.0	42.1
45+	43.4	42.5	41.1*	40.7*
48	43.8	42.7	42.2	41.6
50	43.7	42.5	42.0	41.7
52	43.7	41.8*	42.1*	41.0*
56	43.9	42.9	42.4	41.4*
60	43.9	42.7	42.6	41.8
64	43.1	41.6	41.2	42.0
68	43.7	43.0	42.8	42.3
72	43.2	42.6	41.9	42.2
76	43.5	41.5	39.9	
80	43.3	41.9	41.1	
84	43.5	43.0	40.8	
88	43.4	43.4	40.0	
92	41.8	41.5	38.6	
96	41.7	41.8	38.8	
100+	41.6	41.2	38.2	
104	42.6	39.4*	37.6*	

<sup>\*</sup> Different from control at P < .05 level of significance.

TABLE II

#### 2-YEAR FEEDING STUDY IN CD\*1 MICE WITH MBC

#### MALE

#### MEAN BODY WEIGHT GAIN(g)

M	EAN BUD	I WEIGHT	GAIL (8)	
				VII
Group:	I	III	v	7500-
	Control	500  PPM	1500 PPM	3750 PPM
Time on Test Weeks				
0+- 1	1.9	1.8	2.1	1.5*
1- 2	1.9	1.6	1.5*	2.1
2- 3	1.4	0.9*	0.6*	0.3*
3- 4	0.5	1.1*	0.9*	1.1*
4- 5	1.0	1.2	1.4	1.1
5- 6+	0.9	0.8	0.6	0.9
6+- 7	0.5	0.2*	0.7	0.4
7- 8	0.5	0.8	0.4	0.9
8- 9	-0.2	0.5*	0.9*	0.3
9-10	1.5	-0.3*	0.2*	0.3*
10-11	-1.0	-0.3	-1.3	-2.1
11-12	0.5	0.7	1.0	1.8*
12-13	0.3	0.2	0.5	0.1
13-14	0.8	1.0	0.8	0.9
14-15	-2.6	$-1.5^{\circ}$	-1.0*	-2.5
15-16	2.4	1.8	1.7	3.1
16-17	0.2	0.4	-0.4	0.1
17-18	0.9	0.8	0.4	0.6
18-19	0.4	0.0*	0.8	0.5
19-20	0.8	0.5	$-0.2^{*}$	0.9
20-21	-0.7	-0.5	0.1	-1.2
21-22	0.9	1.1	0.4	0.5
22-23	0.7	0.1	0.6	1.1
23-24	-0.1	0.4	0.3	-0.0
24-25	0.1	-0.3	-0.3	-0.3
25 - 25 +	0.7	0.8	0.7	1.3*
25 + -28	0.5	0.5	0.9	0.1

<sup>\*</sup> Different from control at P < .05 level of significance.

19a

## TABLE II-Continued

Group:	I Control	III 500 PPM	V 1500 PPM	VII 7500- 3750 PPM
Time on Test Weeks				
28-30	1.2	0.9	0.6*	0.7*
30-32	0.6	-0.3*	-0.3*	0.4
32-34	-3.3	-2.3*	-2.7	-1.6*
34-36	2.6	1.5*	1.8*	1.3*
36-38	-0.5	-0.2	-0.3	-0.9
38-40	-0.4	0.4*	0.7*	0.7*
40-42	-0.3	-0.4	-1.5*	-1.1*
42-44	1.2	0.9	1.1	1.3
44-45+	-0.3	-0.0	-1.0*	-1.3*
45+-48	0.4	0.1	1.1*	1.0
48-50	-0.0	-0.2	-0.1	-0.2
50-52	-0.0	-0.9*	-0.4	-0.8*
52-56	0.2	1.0	0.3	0.1
56-60	-0.2	-0.3	-0.2	-0.0
60-64	-1.3	-1.2	-1.7	-0.4
64-68	0.1	0.6	1.0	-0.3
68-72	-0.8	-1.0	-1.3	-0.7
72-76	-0.5	-1.4	-2.2	
76-80	-0.9	0.2	1.2*	
80-84	-0.1	0.6	0.1	
84-88	-0.5	0.4	-0.8	
88-92	-2.5	-1.5	-2.2	
92-96	-0.8	-0.4	-0.4	
96-100+	-1.1	-1.0	-0.9	
100+-104	0.3	-1.1	-0.1	
0-25	14.3	13.7	13.6	13.7
0-52	16.0	14.2*	14.6	13.4*
0-72	15.5	15.0	14.7	14.9
0-104	14.8	12.3	10.5*	

<sup>\*</sup> Different from control at P < .05 level of significance.

#### APPENDIX D

### NATURAL RESOURCES DEFENSE COUNCIL, INC. 25 Kearny Street San Francisco, California 94108 415 421-6561

#### November 5, 1982

Washington Office 1725 I Street, N.W. Suite 600 Washington, D.C. 20006 202 223-8210 New York Office 122 East 42nd Street New York, N.Y. 10168 212 949-0049

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Anne Gorsuch, Administrator Environmental Protection Agency 401 "M" Street, S.W. Washington, D.C. 20460

Therese Murtagh, Chief Information Services Section Environmental Protection Agency 401 "M" Street, S.W. Washington, D.C. 20460

Dear Ms. Gorsuch and Ms. Murtagh:

This is a request under the Freedom of Information Act (FOIA), as amended, (5 U.S.C. § 552) in conjunction with § 10 of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) (7 U.S.C. § 136(h)). It is made on behalf of the following organizations: American Federation of Labor and Congress of Industrial Organizations (AFL-CIO); Natural Resources Defense Council, Inc.; Environmental Defense Fund; Friends of the Earth; National Coalition against Misuse of Pesticides; California Agrarian Action Project; and California Rural Legal Assistance.

On behalf of their members, these organizations request health and safety data retrievable from the files of the Environmental Protection Agency for the following pesticides: aldoxycarb, glyphosate ("Roundup"), permethrin, DD and telone. In particular, we request all studies, status reports and EPA documents relating to carcinogenicity, mutagenicity, neurotoxicity and teratogenicity and other reproductive effects of the abovenamed pesticides as referenced in § 10(d)(1) of FIFRA, including materials that have received accession numbers, EPA and evaluations of these materials and any pertinent submissions from pesticide registrants to EPA.

This request includes, but is not limited to, the following glyphosate studies:

Studies performed by Industrial Biotest (Reference source: Monsanto-Glyphosate (471 AC) IBT Validation Statuts Sheet, pages 151-153):

EXHIBIT "A"

Study Type	IBT Number	Study Date	Acct. Number
Subchronic Dermal	A-1549	07-18-72	094176
Subchronic Dermal Rabbit	A-2144	01-11-73	094176
Acute Oral Rabbit	A-2277	12-06-72	094176
Subchronic Dermal Rabbit	A-2468A	01-11-73	094176
Chronic Feeding Rats	B-564	01-14-74	094161
Reproduction Rats	B-566	07-26-73	094161
Carcinogenicity Mice	B-469	09-19-73	094161
Subchronic Oral Rats	B-1020	11-29-73	094161
Subchronic Oral Dogs	C-1021	06-19-72	094176
Mutagenicity Mice	E-567	01-24-72	094161
Residue Quail	E-1753	09-19-72	094171
Chronic Feeding	J-565	11-30-73	094161
Teratogenicity Rabbits	J-568	06-30-72	094161
Fish/Wildlife Study	R-2278	11-02-72	094161
<b>Acute Inhalation Rats</b>	T-2279	11-07-72	094161
Acute Subcutaneous Mice	601-5848	12-16-71	_
Cholinesterase Rats	601-6527	03-07-75	094688
Fish/Wildlife Study	621-4177	11-13-73	-
Fish/Wildlife Study	621-5412	08-01-74	094688
Mutagenicity Rats/Mice	623-7508	11-18-75	_
Residue	632-3894	10-16-73	094180
Mutagenicity	633-7507	02-20-76	_
Recombin. Assay	683-7801	08-05-76	-

#### EXHIBIT "A"-Continued

Study Type	IBT Number	Study Date	Acct. Number
Toxicity & Reproduction			
Chickens	651-3917	06-18-74	094688
Teratogenicity Rabbits	651-5275	08-28-74	_
Acute Inhalation	663-6290	07-09-75	094683
Subchronic Inhalation	633-6290	07-24-75	_
	(74-116B)		
Fish/Wildlife Study	665-3629	07-26-73	094171
Neurotoxicity Chickens	8580-9117	12-17-76	5G1862
Dominant Lethal Mice	8533-8920	_	_
Teratogenicity Rabbit	8580-8921	_	_
2-Year Chronic Oral Dog	8580-8922	_	_
3 Gen. Repro. Rats	8533-8923	_	_

Studies referred to or submitted in support of a tolerance amendment for glyphosate (reference source: Federal Register 43164, Vol. 46, No. 166, Thursday, August 27, 1981):

oral LD<sub>50</sub> (rabbit); 90-day feeding (rat); 90-day feeding (dog); teratology (2 rabbit); teratology study (rat); 2-year feeding study (dog); 18-month feeding study (mouse); 2-year feeding study (rat); Ames assay; rec-assay; rec-assay (B. subtilis); Ames Test (Salmonella); dominant lethal assay (mouse)

Studies from a California Department of Food and Agriculture bibliography of Roundup data titles:

Human Patch Test with CP 70139 Formulation (MON 2139);

Acute Contact and Oral Toxicities of CP 67573 and (MON 2139) to Worker Honey Bees (9/16/72);

Summary of CP 67573 Metabolism Studies in Plants and Animals;

OP 67573—the Distribution and Excretion of CP 50435-14C (CP 6/5/73 Metabolite) by the Rat:

The Duration of MON-0573 Biological Activity in Soil;

- The Photolysis Run-Off and Leaching of MON-0573 on or in the Soil;
- Soil Binding and Phytotoxicity of MON-0573 and Its Metabolites on Soil;
- The Rate of Dissipation of MNO-0573 and its Metabolites on Soil;
- Degradation and Metabolism of MON-0573 in River and Lake Bottom Sediments and Surface Water;
- Run-off of MON 0573 from Inclined Soil Beds;
- Roundup Herbicide Forest Ecosystem Study, Monsanto Report MSI-1578;
- Chronic Toxicity of Glyphosate to the Fathead Minnow, E.G.&G. Bionomics Aquatic Tox. Lab. Oct. 1975 Monsanto Company;
- Data in Support of Tolerance Requests for Glyphosate in Potable Water, Fish and Shellfish;
- The Effect of Glyphosate on Nitrogen Fixation and Nitrification in Soil with Time;
- Kinetics of "Aged" 14C-Glyphosate in a Model Aquatic Ecosystem;
- G-3780A Surfactant: Biodegradation in Natural Waters;
- The Measurement of Pesticide Drift Resulting from Aerial Applications and the Product Activity Level on Sensitive Non-Target Plants;
- Effects on Glyphosate on Food Preference—Blacktailed Deer; and
- Residue Study with 14C-CP 67573 in Bobwhite Quail.

We request that work begin on this immediately. In particular we request that the affected industry be notified immediately of the specific studies listed above. In addition, we request that all time periods and deadlines in the statute and regulations be strictly adhered to. During the past, in a prior FOIA request, a several-

month delay occurred between our initial request and notification of the industry. This delay made it necessary for the requestors to file a lawsuit. We hope this type of judicial action will not be necessary now.

Under the Freedom of Information Act and FIFRA, we are entitled to all of the requested materials. While FOIA contains an exemption for certain matters that are trade secrets, Congress specifically provided in the 1978 amendments to § 10 of FIFRA that the materials being requested here are not trade secrets, and that members of the public have the right to obtain pesticide health and safety data on the acute and chronic effects from pesticide exposure.

However, if all or any part of this request is denied, we request, as the Act requires, a list of the specific statutory exemptions upon which the EPA is relying to withhold information. If the EPA determines that some portions of the requested material are exempt, we request, in accordance with the Act, that we be provided with the remaining non-exempt portions. We, of course, reserve the right to appeal any decision to withhold information and expect that you will list the address and office where such an appeal can be sent.

The requesting organizations are prepared, if necessary, to pay reasonable costs for locating and reproducing the requested documents. However, pursuant to amendments to the FOIA which provide for a reduction or waiver of fees if it is "in the public interest because furnishing the information can be considered as primarily benefitting the public," we request such a waiver of fees. The members and clients of the requesting organizations regularly are exposed to these pesticides, risking adverse health and safety effects. These documents are necessary in order to independently review the sufficiency of the tests performed on these chemical agents and thereby advise and protect our members concerning potential health risks, such as cancer, birth defects and genetic mutations.

In addition, the health and safety properties of these pesticides is a matter of ongoing public debate. Release of this information will contribute to this debate by increasing public awareness of the possible adverse effects resulting from continued exposure to these toxic substances. Further, it is our intention, once this data is received, to have it reviewed by a body of independent scientists to determine whether the tests involved were adequately performed. Thus, disclosure of the data is required to better protect the public and our members by ensuring that the health and safety tests here conducted by the chemical industry were adequate for that purpose. Finally, all of the organizations making this request are non-profit, will not benefit financially from this information, and seek to obtain it solely to promote the public interest and well-being.

The Agency waived fees for our previous request. Because of the similarity of these requests, we assume the Agency will again grant a waiver. However, if the Agency refuses to waive fees and if the costs exceed \$1,000, we request permission to review the records that are responsive to this request and then select those documents that we want copied.

Enclosed is our executed affirmation of non-multinational status. As provided in the Freedom of Information Act, we expect the Agency's initial response within ten working days. If you need any further information regarding this request, please contact Al Meyerhoff by telephone at 415/421-6561.

Sincerely,

Albert H. Meyerhoff
Natural Resources Defense
Council, Inc.
Stephen P. Berzon
Altshuler and Berzon

By /s/

ALBERT H. MEYERHOFF

Differe Supreme Court, U.S.
FILED
JAN 19 1984

#### IN THE

## Supreme Court of the United States

OCTOBER TERM, 1983

WILLIAM D. RUCKELSHAUS, ADMINISTRATOR
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY,
Appellant,

V.

MONSANTO COMPANY,

Appellee.

On Appeal From The United States District Court For The Eastern District Of Missouri

BRIEF, AMICUS CURIAE, FOR THE AMERICAN PATENT LAW ASSOCIATION, IN SUPPORT OF THE APPELLEE.

American Patent Law Association, Inc. 2001 Jefferson Davis Highway Arlington, Virginia 22202
Bernarr R. Pravel, President
By
Donald S. Chisum

Donald S. Chisum
1001 Bank of California Center
Seattle, Washington 98164
Its Attorney

## TABLE OF CONTENTS

	L.	'age
AUT	THORITY TO FILE	1
INT	EREST OF THE AMERICAN PATENT LAW ASSOCIATION, INC.	1
I.	NEED FOR CONSTITUTIONAL SAFEGUARDS FOR TRADE SECRETS	. 2
II.	STATE LAW PROTECTION OF TRADE SECRET PROPERTY	3
III.	FEDERAL LAW CONFIRMATION OF TRADE SECRETS .	7
IV.	Conclusion	9

## TABLE OF AUTHORITIES

CASES:	Page
Board of Regents v. Roth, 408 U.S. 564 (1972)	3, 4
Chicago Bd. of Trade v. Christie Grain and Stock Co., 198 U.S. 236 (1905)	7
Chrysler Corp. v. Brown, 441 U.S. 281 (1979)	8
E. I. du Pont de Nemours & Co. v. Christopher, 431 F.2c 1012 (5th Cir. 1970)	4
E. I. du Pont de Nemours Powder Co. v. Masland, 244 U.S. 100 (1917)	1
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CONSTITUTION, STATUTES, REGULATIONS AND RULES:	
Constitution of the United States:	
Amendment V	2, 3
Amendment XIV.	3
5 USC § 552(b)	8
15 USC § 3701	2
18 USC § 1905	8

## **Table of Authorities Continued**

P	age
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## IN THE

## Supreme Court of the United States

OCTOBER TERM, 1983

No. 83-196

WILLIAM D. RUCKELSHAUS, ADMINISTRATOR
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY,

Appellant,

V.

MONSANTO COMPANY,

Appellee.

On Appeal From The United States District Court For The Eastern District Of Missouri

BRIEF, AMICUS CURIAE, FOR THE AMERICAN PATENT LAW ASSOCIATION, IN SUPPORT OF THE APPELLEE.

#### AUTHORITY TO FILE

This brief amicus curiae is submitted by the American Patent Law Association Inc. under Rule 42(2) of this Court. Letters of consent from appellant and appellee are on file with the Clerk of the Court.

# INTEREST OF THE AMERICAN PATENT LAW ASSOCIATION

The American Patent Law Association, Inc. (APLA) is a national society of more than 4600 members of the bars of many States interested in patent, trademark, copyright, trade secret and other laws protecting intellectual property rights. The APLA membership includes attorneys in private practice and those employed by corporations, universities and government.

The APLA has no views on the private interests of the parties hereto but is deeply concerned about the issues of public importance here involved.

This case raises important issues concerning the status of trade secrets and confidential technical information as property.

This brief is filed in support of the position urged by appellee Monsanto and adopted by the court below that confidential research data accumulated at great expense by a private person constitutes a property right within the meaning of the Fifth Amendment to the United States Constitution.

I.

Trade secrets in technical information have long enjoyed status in the law as a species of intellectual property. Both state and federal law recognize and protect rights in such property. Today, it is generally recognized that this country needs to devote more resources to technological innovation and development in order to maintain our basic economic, social, and political values. See, e.g., the Stevenson-Wydler Technology Innovation Act of 1980, 15 U.S.C. 3701 (1982). Confirmation by this Court of the status of trade secrets as property will inspire confidence in those contemplating investment in the risk-laden process of research and development. A contrary ruling will send a message of uncertainty. It will exacerbate fears that the fruits of technical research may be snatched by shifting government policy on unconsented use and disclosure of submitted information that is unrestrained by substantive constitutional safeguards. Recognition of property rights in technical information submitted to government agencies will not hamstring the public interest or the regulatory process any more than does the recognition of private property rights in tangibles, such as chattels and land. Such recognition will neither unreasonably restrict competition nor inappropriately extend patent rights which may exist in particular pesticide compounds and processes.

#### II.

This Court has never adopted an inclusive or exclusive definition of "property" for purposes of either the takings clause of the Fifth Amendment or the due process clauses of the Fifth and Fourteenth Amendments. This Court has variously characterized property rights as "those economic advantages . . . which have the law back of them." United States v. Willow River Power Co., 324 U.S. 499. 502 (1945); as "interests . . . sufficiently bound up with the reasonable expectations of the claimant," Penn Central Transp. Co. v. New York City, 438 U.S. 104, 125 (1978); and as "expectancies" that are "sufficiently important." Kaiser Aetna v. United States, 444 U.S. 164, 179 (1979). Property "may take many forms," Board of Regents v. Roth, 408 U.S. 564, 576 (1972), and includes intangible property, such as contracts, Omnia Commercial Co. v. United States, 261 U.S. 502, 508 (1923). While property includes a bundle of rights, such as the right to use and the right to convey, a "fundamental element" of property is the right to exclude others from enjoying the property without the owner's consent. Kaiser Aetna v. United States, supra 444 U.S. at 180.

The constitution itself does not create property rights. Such rights arise from "existing rules or understandings that stem from an independent source such as state law." Board of Regents v. Roth, supra 408 U.S. at 577. Thus, at least initially, state law governs the property status of a confidential compilation of technical information.

Well-established state law provides a variety of remedies for unconsented use or disclosure of trade secrets. The definition of a trade secret most commonly adopted by state courts is that in Section 757 of the Restatement of Torts. See, e.g., Ultra-Life Laboratories, Inc. v. L. W. Eames, 240 Mo. App. 851, 221 S.W. 2d 224, 232 (1949). Under the Restatement, a trade secret consists of "any formula, pattern, device or compilation of information which is used in one's business, and which gives him an opportunity to obtain an advantage over competitors who do not know or use it." Section 1(4) of the Uniform Trade Secrets Act provides a similar definition. The subject must be held in secret, though disclosure in confidence to another does not eliminate the element of secrecy. The primary protection granted to the holder of a trade secret is the right to exclude others who come into possession of the subject through improper means from using or disclosing the subject. The protection has even been held to extend to means of discovery that are not inherently illegal, tortious, deceptive, or in breach of contract. See, e.g., E. I. du Pont de Nemours & Co. v. Christopher, 431 F.2d 1012 (5th Cir. 1970) cert, denied 400 U.S. 1024 (1971) (aerial reconnaisance). However, trade secret protection does not extend to discovery of the subject "by fair and honest means, such as by independent invention, accidental disclosure, or by so-called reverse engineering." Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470, 476 (1974).

Commentators find it useful to distinguish two types of trade secrets. E.g., 2 R. CALLMANN, The Law of Unfair Competition, Trademarks and Monopolies § 52 (3d ed. 1968); Note, Constitutional Limitations on Govern-

ment Disclosure of Private Trade Secret Information, 56 Indiana L.J. 347, 355 (1981). On the one hand are "hard core" trade secrets, "commercially valuable, secret information relating directly to the productive process that can be said to be the end product of innovation." This is technical information, pursued for its own sake and often of lasting value to human-kind. The testing data at issue in this case falls into this category. On the other hand are internal business facts. This is information on employees, costs, prices, profits, customers, etc., generated by a firm as an incident to its business. Both types of trade secrets may give a firm competitive advantages, and both may be protected under state law. However, the case for property status is clearly strongest as to "hard-core" trade secrets. See Connelly, Secrets and Smokescreens: A Legal and Economic Analysis of Government Disclosures of Business Data, 1981 Wis, L. Rev. 207, 240-245. Such secrets have independent value; they can be and regularly are licensed or sold for substantial consideration.

The existence of expectations of protection based on state law is more important for constitutional purposes than the labelling as property. However, in most instances, state courts do actually characterize trade secrets as "property." This is true as to the law of Missouri, the state of the principal place of business of the appellee Monsanto. Harrington v. National Outdoor Advertising Co., 355 Mo. 524, 196 S.W.2d 786, 791 (1946); Godefroy Mfg. Co. v. Lady Lennox Co., 134 S.W.2d 140, 141 (Mo. App. 1939). Commentators are virtually unanimous in conferring a property status on trade secrets, particularly those which are of the "hard-core" variety. E.g., R. MILGRIM, Trade Secrets § 1.01. Trade secrets are treated as property within the meaning of various state doctrines and statutes. See R. CALLMAN, supra, § 51.1

n. 25 ("this property in a trade secret is, like other property, assignable, taxable, capable of being a res of a trust and of passing to a trustee in bankruptcy"). At least one state court has held that trade secrets in a confidential compilation of technical information constitute property within the meaning of its state constitution. Mountain States Tel. & Tel. Co. v. Dep't Pub. Serv. Reg., 634 P.2d 181 (Mont. 1981). Thus, trade secrecy is more than a potential cause of action under state tort law. Compare Paul v. Davis, 424 U.S. 693, 712 (1976).

Virtually all judicial statements denying property status to trade secrets trace to a single source—Justice Holmes' opinion in E. I. du Pont de Nemours Powder Co. v. Masland, 244 U.S. 100 (1917). In Masland, an employer sued to enjoin a former employee from improperly using a secret process. The employee appealed from a preliminary injunction restricting disclosure by the employee of the process to his own expert witnesses. The Court affirmed in a short opinion. Appellant's counsel argued that the case posed a conflict between a right of property and a right to make a full defense and that to grant such a preliminary injunction prejudged the merits and was unfair as to a defendant who wished to prove that there was no true trade secret. Justice Holmes responded:

The word 'property' as applied to trademarks and trade secrets is an unanalyzed expression of certain secondary consequences of the primary fact that the law makes some rudimentary requirements of good faith. Whether the plaintiffs have any valuable secret or not the defendant knows the facts, whatever they are, through a special confidence that he accepted. The property may be denied, but the confidence cannot be. Therefore the starting point for the

present matter is not property or due process of law, but that the defendant stood in confidential relations with the plaintiffs. 244 U.S. at 102.

Justice Holmes did not in the Masland passage deny the property label to trade secrets. He simply asserted that preliminary relief would be in order given the admitted existence of a prior confidential relationship. The passage, read in context, only emphasizes that the defendant could and was denying the existence of a trade secret (hence the property) but could not deny the existence of the confidence. Further, the passage emphasizes that use of the property label does not aid the analysis of the particular legal issue before the Court, which was the standard case of the former employee competing with his former employer. Commentators agree that it is improper to rely on the Masland statement as a general pronouncement of the non-property status of trade secrets. Connelly, supra at 242 n. 166; CALLMAN, supra § 51.1. In other cases, Justice Holmes had no compunction in characterizing as property confidential compilations of information that state law protected as a trade secret. Chicago Bd. of Trade v. Christie Grain and Stock Co., 198 U.S. 236, 250-251 (1905). And, of course, this Court's characterization of common law trade secret rights is not definitive as to state courts and state law. Erie R.R. Co. v. Tompkins, 304 U.S. 64 (1938).

#### III.

Federal law has traditionally been as solicitous of interests in trade secrets as has state law. This solicitude further contributes to the expectations of property protection created by state law.

Various statutes and regulations recognize the importance of trade secrets. Two are particularly worthy of mention. The Trade Secrets Act makes it a crime for an officer or employee of the United States to disclose "to any extent not authorized by law" information concerning, inter alia, trade secrets and confidential statistical data. 18 U.S.C. § 1905. This Court gave a liberal interpretation to this statute in Chrysler Corp. v. Brown, 441 U.S. 281 (1979), reasoning that it applied to official agency action as well as to frolics by individual government employees. While the Court declined to infer a private cause of action for its enforcement, it did refuse to recognize any broad inherent power of federal administrative agencies to use interpretative regulations to "authorize by law" disclosure of trade secrets and confidential data.

The Freedom of Information Act expressly exempts from mandatory disclosure "trade secrets and commercial or financial information obtained from a person and privileged or confidential." 5 U.S.C. § 552(b). While this is an exception to mandatory disclosure rather than an injunction against disclosure, Chrysler Corp. v. Brown, supra, it nevertheless dovetails with the Trade Secrets Act to further trade secret owner's expectations.

The decisions of this Court also recognize the importance of trade secrets. Foremost is Kewanee Oil Co. v. Bicron Corp., supra. In Kewanee, this Court held that state trade secret protection was not preempted by federal patent policy, even as to subject matter potentially eligible for a patent. This Court emphasized that patent law and trade secret law worked hand-in-hand in creating incentives to innovation. Significantly, this Court referred at least twice to trade secret protection as a type of "intellectual property."

#### IV.

#### CONCLUSION

For the foregoing reasons it is submitted that trade secrets and confidential technical information are "property" within the meaning of the Fifth Amendment.

Respectfully submitted,

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## In the Supreme Court of the United States

October Term, 1983

WILLIAM D. RUCKELSHAUS, ADMINISTRATOR,
UNITED STATES ENVIRONMENTAL
PROTECTION AGENCY,
Appellant,

VS.

MONSANTO COMPANY, Appellee.

On Appeal From the U.S. District Court for the Eastern District of Missouri

BRIEF OF AVCO CORPORATION
AS AMICUS CURIAE

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## TABLE OF CONTENTS

Interest of Amicus Curiae Avco Corporation, Lycoming Division	1
Statement of the Issue	4
Summary of Argument	5
Argument—	
The District Court Properly Ruled An Unconsti- tutional Taking Is Effected By A Government Agency's Use And/Or Disclusure Of Trade Secrets Required To Be Given It	7
Secrets Required to be Given it	-
Conclusion	23

## TABLE OF AUTHORITIES

## Cases

Aris Gloves, Inc. v. U.S., 420 F.2d 1386 (Ct. Cl. 1970)	21
Balelo v. Klutznick, 519 F. Supp. 573 (S.D. Calif. 1981)	20
Currin v. Wallace, 306 U.S. 1 (1939)	18
Eyherabide v. U.S., 345 F.2d 565 (Ct. Cl. 1965)	21
Frost v. Railroad Commission, 271 U.S. 583 (1926)19	-20
Gannett Company v. DePasquale, 443 U.S. 368 (1979)	19
Heart of Atlanta Motel v. U.S., 379 U.S. 241 (1964)	17
Kaiser Aetna v. U.S., 444 U.S. 164 (1979)	10
Loretto v. Teleprompter Manhattan CATV Corp., 73 L.Ed.2d 868 (1982)	20
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Pennsylvania Coal Company v. Mahon, 260 U.S. 393 (1922)	, 20
Shechter Poultry Corp. v. U.S., 295 U.S. 495 (1935)	18
Standard Airlines, Inc. v. C.A.B., 177 F.2d 18 (D.C. Cir. 1949)	19
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on other grounds 616 F.2d 662	20

# Constitutional Provisions

## 

#### Miscellaneous

123 Congressional Record 25711	15
Hearings Before the Subcommittee On Export Opportunities and Special Small Business Problems of the	
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§ 757, Restatement of Torts	3

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VS.

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On Appeal From the U.S. District Court for the Eastern District of Missouri

# BRIEF OF AVCO CORPORATION AS AMICUS CURIAE

# INTEREST OF AMICUS CURIAE AVCO CORPORATION, LYCOMING DIVISION

Avco Corporation, Lycoming Division, based in Williamsport, Pennsylvania, is a manufacturer of airplane piston engines. As such, it conceives, researches, designs, develops, tests and manufactures both airplane engines and replacement parts for such engines. It is subject to regulations of the Federal Aviation Administration (FAA) in respect to obtaining a "type certification" for each model engine it intends to market. This because under regulations adopted by the FAA pursuant to authorization of the Federal Aviation Act, Title 49, U.S.C. §§ 1421, et seq., before any aircraft engine or replacement part is introduced into air commerce, it must first be approved by the FAA. Research, development, design and testing of such engines

is at a cost of from six to ten million dollars for each such engine model. Avco considers such designs as valuable trade secrets and takes appropriate steps to retain the confidentiality of such designs.

In about 1972, the FAA adopted certain regulations allowing third persons to manufacture replacement parts for aircraft engines if the FAA granted such third persons a Parts Manufacturer's Approval (PMA). This was pursuant to what is now FAR § 21.303 (Subpart K. Part 21) 14 CFR 85 (1983). Such PMA's could be given the third persons on a number of grounds, including "identicality" whereby the third persons would submit to the FAA drawings of the part for which the PMA was sought and, if a proper showing was made by the applicants as to the "identicality" of the design so submitted with the drawing which the FAA had obtained from the type-certificate holder, the PMA would issue. In effect, the PMA applicant receives a "free ride", with the original engine manufacturer bearing all costs of research, development, testing, certification and market development.

In practice, this has evolved into a process where the FAA requires the original engine manufacturer, such as Lycoming, to either keep its drawings on file with the FAA and/or available to the FAA for such comparison purposes. In addition, contrary to its own rules, the FAA no longer requires the "showing" to be made by such third persons. Rather, it informally - and unauthorizedly - reveals to third persons what appears on the type-certificate holder's drawing. The FAA has recognized its practice is probably illegal, and in recent testimony before a House of Representatives subcommittee, it stated it anticipates litigation challenging its aforesaid practices. See Hearings Before the Subcommittee On Export Opportunities and Special Small Business Problems of the Committee On

Small Business, House of Representatives, 97th Congress, Second Session, at pp. 286, 289, 296-7.

The Avco drawings and designs required to be submitted to the FAA are trade secrets that fulfil all requirements set forth by § 757, Restatement of Torts, and by the many cases in numerous jurisdictions recognizing both the existence and value of such trade secrets and the protection to be afforded to them.

Avco-Lycoming has registered objection to the FAA in respect to its practice of demanding parts drawings for the purpose of comparing third persons' drawings submitted for PMA approval; to the FAA's failure to require a "showing" by the prospective PMA applicant; and to the FAA's informal but absolutely prohibited and unauthorized practice of revealing in one way or another to PMA applicants details of the manufacturer's designs and drawings. Avco-Lycoming has protested to the FAA, inter alia, that its practices effect an unconstitutional taking of property without just compensation.

The present case before the Court has as its chief issue the question of whether or not a governmental agency can use and/or disclose trade secrets required to be submitted to it. Avco-Lycoming does not challenge the right of the federal government to require submission to it of this information so that the government may type-certificate engines to be introduced into air commerce. What we are concerned with is the government's illegal, unconstitutional use and disclosure of trade secrets to and for the benefit of third persons. It is on that basis and upon that constitutional question that this amicus brief is submitted.

Both the Solicitor General and counsel for respondent Monsanto Company have in writing consented to submission of this *amicus* brief by Avco-Lycoming.

### STATEMENT OF THE ISSUE

Although several issues are raised in this appeal, Avco Corporation, as amicus curiae, addresses only one main issue:

Was the district court correct in ruling an unconstitutional taking is effected by a government agency's use and/or disclosure of trade secrets it requires be submitted to it?

We respectfully submit this should be answered YES.

### SUMMARY OF ARGUMENT

All citizens hold property subject to certain limitations which may be imposed thereon for the public good. The question is at what point such limitations so intrude upon property rights as to become a taking, or to violate due process. Put another way, at what point must the public at large, rather than the property owner, pay for the desired limitation.

Where there is a conflict between an exercise of the Commerce clause and rights under the Takings clause, the Takings clause prevails. To ascertain if there is a conflict, general propositions are not relied on. Rather, the Courts examine the "particular facts" of the matter and the "degree" of the Congress' intrusion on property rights in its attempt to exercise Commerce clause powers.

Here, to uphold (a) the use or consideration provisions and (b) the disclosure provisions, two different rationales for the Congress' action are given, a separate one for each. In respect to (a), the use or consideration provisions, it is said the Congress was attempting to promote competition and eliminate duplication (purposes which are themselves internally inconsistent in economic theory). However, a closer, more realistic examination shows that no matter what rationale is offered, there is a naked, unabashed taking from the submitting manufacturer. The taking is accomplished by the mandated sharing and imparting of valuable trade secrets with competitors. Promotion of competition and elimination of duplication cannot be constitutionally accomplished by simply stripping a citizen of his property and handing it over to his competitors. Nothing could be better proof of this unconstitutional taking than the statutory scheme itself in which the Congress

(1) recognizing compensation had to be made, provides for a procedure whereby payment is made to the submitting manufacturer, and (2) provides for such compensation to be paid by private, not government, funds - a sure indication the taking was for private purposes and not for a public use, as required by the Fifth Amendment.

In respect to (b), the disclosure provisions, the rationale used to justify it is based fundamentally on a distrust of the EPA's capabilities and competency. It is claimed dissemination to unidentified members of the public is necessary to enable the public to oversee or monitor the EPA in its work. However, if an agency created and funded by the Congress is unable to perform its functions without public oversight, the appropriate and reasonable means to correct these deficiencies is to take steps to cure the agency's inabilities. It is not to scatter the submitting manufacturer's trade secrets to the four winds in the hope that persons finding them may then be able to aid the agency in its work. Such method throws the entire cost of the agency's incompetence or disabilities on the submitting manufacturer. Further, such delegation of power is not to a well-defined group or body. Rather, it is to unnamed, unidentified members of the public. Nor does the statute offer any standard by which the public's feelings will either influence or bind the agency.

Complaint is here made of an "unconstitutional taking." Both words are to be emphasized. It is clearly a "taking" if only because the Congress itself provided for compensation to be made. It is "unconstitutional" if only because the Congress has itself provided private parties must pay such compensation, proof it is not for a public use. Both provisions are in the statute itself. Even if not unconstitutional, it is still a taking.

### ARGUMENT

The District Court Properly Ruled An Unconstitutional Taking Is Effected By A Government Agency's Use And/Or Disclosure Of Trade Secrets Required To Be Given It.

Surely the arguments appellant makes to uphold this legislation are among the strangest ever presented to this Court.

To uphold the use (or consideration) provisions, appellant makes an utterly inconsistent economic argument, i.e., the Congress was supposedly seeking to promote competition while eliminating duplication, an internal contradiction in economic concepts. As to the disclosure provisions, according to appellant, the legislative scheme which appellant seeks to have this Court uphold presents a unique picture in which the Congress believes the regulatory agency it created to be inept and incompetent. It therefore finds it necessary to require the regulated industry to yield up its trade secrets to unidentified members of the public and scientific community so they can monitor such agency's activities.

Other arguments are equally strange: Appellant contends this is not a taking; yet the Congress makes specific provision to pay compensation to the submitting manufacturer for the property taken. Appellant argues this is not for private purposes but is for a public use; yet the Congress provides for private parties - not the government - to make payment to the submitting manufacturer.

We certainly acknowledge that the Congress in regulating commerce has a wide discretion to choose appropriate and reasonable means to accomplish its ends. However in this case, the means chosen are specifically based on the supposed ineptitude and incompetency of its own regulatory agency and do not here seem to be appropriate and reasonable. They certainly cannot justify a taking without just compensation. Yet such agency deficiencies are in reality the very bases on which appellant argues to uphold the disclosure provisions.

These unique arguments are made because this case presents a head-on confrontation between the Commerce clause (Art. I, § 8, Clause 3) and the Takings clause (Amendment V). On the one hand is the Congress' undoubted power and authority to impose restrictions and limits upon this industry's introduction of certain chemicals into interstate commerce. No one seriously doubts the Congress' power and authority to do so. On the other hand are the protections afforded each citizen by the Fifth Amendment's Takings clause, requiring that any taking be for a public use and only then when any person so affected is given just compensation.

While some of this Court's more recent cases have dealt with this clash between these two clauses, perhaps none has presented the picture so well or in so clear-cut a manner (and in such precise, lucid language) as Pennsylvania Coal Company v. Mahon, 260 U.S. 393 (1922). The majority opinion was written by Justice Holmes; the dissent by Justice Brandeis. Each argued clearly and articulately the respective positions.

It is true that in *Pennsylvania Coal*, it was the state's police power, rather than the Congress' power under the Commerce clause, that was at issue. But given the expansive interpretations afforded the Commerce clause since 1922, the respective scopes of both police power and Commerce clause can for present purposes be deemed coexten-

sive. In *Pennsylvania Coal*, the state had imposed severe regulations on the ability of coal companies to mine underground in certain areas. The mine owners argued a taking had been effected, a position with which this Court agreed.

After expounding government's need to be able to regulate and the requirement that all citizens' rights of ownership be limited and subject to some degree to the sovereign's ability to regulate for the common good, Justice Holmes stated, 260 U.S., at p. 413:

But obviously the implied limitation must have its limits or the contract and due process clauses are gone. One fact for consideration in determining such limits is the extent of the diminution. Where it reaches a certain magnitude, in most cases if not in all cases there must be an exercise of eminent domain and compensation to sustain the act. So the question depends on the particular facts. The greatest weight is to be given to the judgment of the legislature, but it is always open to interested parties to contend that the legislature has gone beyond its constitutional power. • •

(at p. 415) The general rule, at least is that while property may be regulated to a certain extent, if regution goes too far it will be recognized as a taking. \* \* \*

(at p. 416) We are in danger of forgetting that a strong public desire to improve the public condition is not enough to warrant achieving the desire by a shorter cut than the constitutional way of paying for the change. As we have already said, this is a question of degree—and therefore cannot be disposed of by general propositions.

In large part, Justice Brandeis' dissent did not take issue with Justice Holmes' approach of examining the "par-

ticular facts" and the "question of degree", of not attempting to dispose of the issue with "general propositions". His point of departure was of course his view of those particular facts and the degree of intrusion under the circumstances there presented. See also Kaiser Aetna v. U.S., 444 U.S. 164, 175 (1979).

Where there is conflict between the Commerce clause and the Takings clause, i.e., there has been in the exercise of Commerce clause powers a taking of property, the Takings clause prevails. The Commerce "power like others, must be exercised in subordination to the 5th Amendment. Monongahela Nav. Co. v. U.S., 148 U.S. 312, 336; U.S. v. Lynah, 188 U.S. 445, 465, 471." U.S. v. Cress, 243 U.S. 316, 326 (1916).

With this introduction, we may proceed to examine the "particular facts" of the Congress' legislative regulation here, the "question of degree" to which it intrudes on private ownership.

From a broad or riview, the Congressional legislation authorizes a federal agency to require that anyone wishing to introduce certain new products on the interstate market must first register them. This is done by requiring a prior submission to the agency of certain information, research and test data about the new product. The agency must then approve the new product. Little or no objection is raised as to the government's authority to require such submission and approval.

The manufacturer's information, research and test data for such new products are obtained, gathered and compiled at significant cost and often after years of research. They legitimately qualify as trade secrets. If the information and data so warrant, agency approval is ob-

tained, the new product is registered and the submitting manufacturer can then market the product.

In the agency's hands, however, the legislation authorizes, first, the submitting manufacturer's information, research and test data to be used to support the subsequent applications of other persons without the permission of the original, submitting manufacturer. In addition, the agency is also authorized (and even directed) to make such "health and safety" data available to members of the public as well as to other federal agencies.

Thus, EPA's use (or consideration) and/or disclosure of appellee's trade secrets takes two forms: (1) Its use (or consideration) under § 3(c)(1)(D), 7 U.S.C. § 136a (c)(1)(D); and (2) its disclosure under § 10(b) and (d), 7 U.S.C. § 136h(b) and (d), and last sentence § 3(c)(2)(A), 7 U.S.C. § 136a(c)(2)(A) (1982).

Interestingly, appellant employs two different rationales - a separate one for each of these two aspects - to justify this exercise of Congressional power: For the use (or consideration) aspect under  $\S \ 3(c) \ (1) \ (D)$ , it claims the Congress was attempting to promote competition and at the same time eliminate "needless duplicative testing" of pesticides already registered, see p. 12, Appellant's Brief. For the disclosure aspect under  $\S \ 10(b)$  and (d) and  $\S \ 3(c) \ (2) \ (A)$ , it claims the "health and safety data" are necessary so that the public and the scientific community can monitor the EPA's activities and in effect participate in or oversee the EPA's decisions, see pp. 13-14, Appellant's Brief.

We may briefly examine each of these claimed rationales:

Use (or consideration) authority under § 3(c)(1)(D). No one doubts the authority and power of the Congress to

promote competition. To this end, the Congress has of course been repeatedly upheld in respect to the constitutionality of its legislation removing restraints of trade. This is unquestionably a proper function of the Congress in regulating commerce.

However, it is one thing to remove or regulate against restraints of trade so as to promote competition. It is quite another to decree that a company or an individual, having developed at substantial expense to itself a piece of valuable property giving it a competitive edge, must disgorge that property, yield it up to a government agency if it is to be marketed, and allow the government agency to distribute it to other persons, all in the name of supposedly promoting competition and eliminating duplication of effort.\*

While the Congress certainly can promote competition by setting ground rules in the conduct of business and legal relations, it cannot take property away from a citizen, distribute it to that citizen's competitors in the name of promoting competition, and not expect to pay for the privilege of doing so. No amount of theoretical, after-the-fact rationalization can justify legislation which "mandate[s] the forced sharing of property and markets created by one person for the benefit of private parties", Monsanto Company v. Acting Administrator, 564 F. Supp. 552, 566 (E.D. Mo. 1983). The district court properly overruled this strictly theoretical argument in view of the actual reality of an unabashed taking for private purposes.

<sup>\*</sup>As noted at the outset, a question of economic theory is raised: Are not the supposed dual goals of promoting competition and eliminating duplication inconsistent with each other? Competition presupposes duplication by similar producers. It must be conceded, however, this inconsistency is here solved by simply depriving the producer of its product and distributing it to its competitors who thereby get a "free ride".

If anything would indicate that the Congress itself knew and understood it could not thus deprive a citizen of his property constitutionally, it is that provision which the Congress itself included providing for payment by the "metoo" applicant to the submitting manufacturer, albeit through the disputed method of binding arbitration, § 3(c) (1) (D) (ii), Title 7, U.S.C. § 136a(c) (1) (D) (ii). The mere fact that the Congress provided for payment to the submitting manufacturer - even if the method is here disputed - is almost positive proof that the Congress itself understood it was providing for a taking and just compensation had to be made in some manner to avoid the taint of unconstitutionality. And the further fact that the Congress provided for private parties to make the compensation is equally positive proof that the taking is for private, not public, purposes. See discussion below.

On the question of whether this is a private use or a public use, the statutory scheme of payment by private parties is certainly a clear indication the Congress knew it was for private use. If it is for a private use, it is clearly unconstitutional and cannot be upheld under any means. If it is for a public use, one of the preconditions for a taking under the exercise of eminent domain has been fulfilled and just compensation is required. As previously stated, the Congress clearly recognized this by its binding arbitration provision affording payment to the submitting manufacturer. While our own particular view is agreement with the district court that it is indeed a private use (indicating the taking is clearly unconstitutional), this is not strictly necessary to our position that it is nevertheless a taking. Even if it be found it is public use, just compensation must be made.

In this respect the trial court, after several weeks of trial and the introduction of voluminous evidence, concluded in respect to the claimed justification that the Congress was supposedly attempting to promote competition, 564 F. Supp., at p. 566:

The Court also finds that  $\S 3(c)(1)(D)$  unabashedly operates to further a private purpose. Internal use of Monsanto's data can only enrich its competitors. The public stands little to gain from  $\S 3(c)(1)(D)$ . This is not a situation where competition is sparse or non-existent, to the contrary, the trial record amply demonstrates the competition and the pesticide industry as healthy and vibrant.

The Court is aware of the deference which must be shown Congressional pronouncements of what constitutes a public purpose. Berman v. Parker, 348 U.S. 26, 32, 75 S. Ct. 98, 102, 99 L. Ed. 24 (1954). Nevertheless, the Court would be abdicating its responsibility to follow the Constitution if it did not rationally analyze laws which, in the name of public policy, mandate the forced sharing of property and markets created by one person for the benefit of private parties. Thompson, 300 U.S. at 78-79, 57 S. Ct. at 375; U.S. v. Carolene Products, 304 U.S. 144, 147, 58 S. Ct. 778, 780-81, 82 L. Ed. 1234 (1938).

The facts fully support the district court's findings and conclusions in this respect. How much competition is necessary? There was ample competition, with many compenies submitting data and seeking registration for new products. See, e.g., Finding of Fact No. 37, 564 F. Supp., at p. 560. But even if there were little or no competition, the Congress could not deprive a citizen of property and distribute it to others ("mandate the forced sharing of property", 564 F. Supp., at p. 566), such as is done here, without making just compensation. Certainly the Congress itself recognized this.

Additional indication that the taking is for private purposes is the unquestioned fact that it is the private parties themselves, not the government, who are required by the statute to make payment for such "free ride". What further proof is necessary to show this is not only a taking, but one for private purposes? The statute itself thus shows the unconstitutional nature of this scheme.

Disclosure authority under § 10(b) and (d) and § 3(c) (2) (A). In respect to the disclosure provisions of the "health and safety data" under § 10(b) and (d) and § 3(c) (2) (A), a different rationale is advanced. Here it is stated the public has a right to know this information so as to facilitate its participation in EPA decisions as to whether or not a product is to be registered and allowed to be marketed. In other words, as is set forth above, the Congress having created a federal agency, supposedly believes such agency to be so inept, so inefficient and so incompetent that it will allow unnamed and unidentified members of the public access to confidential information belonging to others so that such members of the public can somehow oversee the EPA's activities. This reasoning was expressed by Senator Kennedy in his remarks of July 29, 1977, 123 Congressional Record 25711:

Of particular significance in the bill as reported is the provision for public disclosure of the safety testing data on pesticides submitted to the EPA by industry. While providing for sufficient protection of "trade secret" information relating to individual pesticide products, this provision will allow for public scrutiny of the EPA's regulatory effort. And I submit that the EPA needs all the help it can get in performing this very difficult regulatory task.

As the trial court noted, there is complete labelling provided for on these products, 564 F.2d, at pp. 556, 563,

567. But this is not a mere labelling provision where manufacturers can properly be required to place certain information upon labels. Here the manufacturer makes no claim the labelling requirements are improper. Rather, the manufacturer is here required to submit to the EPA so that it can make available to unidentified members of the public extensive data developed at substantial cost. The acknowledged purpose is that public input is necessary to assist the agency in performing its tasks. Surely this is one of the first times the Congress has provided for such backup of one of its own agencies.

We leave aside for the moment the question of delegation of power to such unnamed, unidentified citizens - itself a serious constitutional issue. Rather, we focus only on whether or not this proposed broadcast of trade secrets, developed at substantial cost (and recognized as trade secrets) by the submitting manufacturer, may be thus accomplished solely so that members of the public can oversee and monitor the agency's activities. It should be noted the district court made reference to the fact that the EPA was competent to handle its assigned tasks and had available to it substantial funds and facilities, without need of disseminating the trade secrets, 564 F. Supp., at p. 567.

It would seem most inappropriate that the very foundation of a Congressional enactment should be the supposed ineptitude and incompetency of its own agency. One would suppose that a government agency, once created and funded by the Congress, will be efficient, competent and able to make its own correct decisions. As stated, the trial court found the EPA could do its assigned job. To presuppose that the agency is unable to do so and requires the dissemination of trade secrets to unidentified members of the public to help it in its work misplaces the emphasis on

what should be done. We do not say the Congress cannot legislate in respect to its own agencies and recognize their shortcomings in this manner. We only say this justification for allowing dissemination of valuable trade secrets is wholly misplaced when done at the cost of the submitting manufacturers.

As long ago as McCulloch v. Maryland, 17 U.S. 316 (1819), this Court ruled the Congress is entitled to adopt any reasonable and appropriate means (within constitutional limits) to accomplish the purposes of the particular exercise of its powers under the Commerce clause. See also Heart of Atlanta Motel v. U.S., 379 U.S. 241, 258-9 (1964). However, if an agency it has created is so inept and so incompetent that it cannot be trusted to act for itself and oversight of its activities must be delegated to unnamed and unidentified members of the public, the reasonable and appropriate means for addressing the problem is to correct that agency's deficiencies. It is not to require submission and then dissemination of a regulated industry member's trade secrets. Such is not reasonably necessary and appropriate to the goal of the agency properly regulating introduction of new chemicals on to the market. Most importantly, even if it be deemed reasonably necessary and appropriate, it is a taking for which just compensation must be made.

Further to be doubted is the indiscriminate delegation of powers to such unnamed and unidentified members of the public so that they may oversee the agency's work. (The record herein indicates such members of the public include appellant's competitors.) While this Court has frequently upheld delegation of powers to non-governmental entities, it has usually been done in respect to a limited, well-defined group of persons; it has rarely, if ever, been done, as here, to the public at large. See

Shechter Poultry Corp. v. U.S., 295 U.S. 495 (1935). As the district court pointed out, Finding No. 63, 564 F. Supp., at p. 563, there is available to the EPA a Scientific Advisory Panel. It is appropriate and reasonable to use such Panel's services. It is not appropriate and reasonable to employ an indiscriminate scattering of trade secrets to the four winds. It is appropriate and reasonable to use the resources available to the EPA. It is not appropriate and reasonable to seek unnamed and unidentified members of the public who will supposedly influence the agency in some undefined manner. See 564 F. Supp., at p. 566.

Not only are the members of the public to whom this data will be given left unnamed and unidentified (rather than defining the bodies or groups to which such delegations of powers have been made, as previously upheld by this Court), but the standards by which their actions or votes will be allowed to influence or affect the EPA are left similarly vague. In those instances where this Court has previously upheld delegation of powers to members of the public, the statutes have specifically identified those members of the public to whom the delegation of powers is made, e.g., Currin v. Wallace, 306 U.S. 1 (1939) (tobacco growers); Sunshine Anthracite Coal Company v. Adkins, 310 U.S. 381 (1940) (coal producers). In addition, the standard under which the public's actions were to influence regulations issued in the name of the government was also set, e.g., two-thirds of those voting. Here, there is no such identity of a well-defined group, nor are there standards by which the undefined members of the public will be able to influence EPA decisions or become binding upon the agency.

When an agency is so inept and so incompetent as to be unable to do its job - the basis of the justification given by appellant for the disclosure authority - the reasonable and appropriate means is to correct that agency's deficiencies. It is not to take trade secrets from members of the regulated industry so as to enable dissemination to unidentified members of the public so that they may do the agency's job for it in some undefined manner.

Cited in support of the justification for the disclosure provisions of § 10(b) and (d) are excerpts of legislative history mentioning the "public's right to know". No decision of this Court has articulated such a "right". In Gannett Company v. DePasquale, 443 U.S. 368 (1979), this Court ruled that insofar as the criminal law was concerned, there is no such thing as a "public right to know", 443 U.S., at pp. 379-380, the right to a public trial being personal to the defendant only. We know of nothing which transfers any such non-existent right into the civil area or can serve as a basis for justifying an otherwise invalid Congressional exercise of Commerce clause powers. Certainly the Congress can, if it chooses, make information properly belonging to the government available to the public in its exercise of the Commerce power, thereby in effect giving the public a "right" to such information. But where such disclosure is at the cost of depriving a citizen of property, any such "public right to know" cannot be made a pretext to avoid making just compensation for a taking.

The argument is also made by appellant, see pp. 29-30, Appellant's Brief, that by submitting such information in order to obtain the authority to market the chemicals in question, the submitting manufacturer has somehow waived its right to object to the dissemination of its trade secrets, even if such dissemination is unconstitutional. This type of argument has long been discredited, see e.g., Standard Airlines, Inc. v. C.A.B., 177 F.2d 18, 20 (D.C. Cir. 1949). Frost v. Railroad Commission, 271 U.S. 583, 593

(1926); U.S. v. Chicago, Milwaukee, St. Paul & Pacific R.R. Co., 282 U.S. 311, 328 (1931); Balelo v. Klutznick, 519 F. Supp. 573 (S.D. Calif. 1981) at p. 580. Rather, we repectfully submit the indiscriminate disclosure of trade secrets to unidentified persons under the pretended justification that such is necessary to oversee and correct the actions of a supposedly incompetent agency are wholly inappropriate and insufficient.\*

Thus, returning to the touchstone case, Pennsylvania Coal Company v. Mahon, examination of the "particular facts" and the "question of degree" of the legislature's acts show clearly there has been a taking which cannot be justified by a purported exercise of Commerce clause powers. As both Justice Holmes and Justice Brandeis indicate, this is the decisive issue. While the judgment of the legislature is to be given the greatest weight, it is not conclusive. If it were, as Justice Holmes noted, the contract and due process (and, he might have added the taking) clauses would all be nullified in the name of the Commerce clause.

Rather, neither of these justifications for this exercise of Commerce clause powers can in this instance be used to

<sup>\*</sup>Appellant's additional arguments that these are not trade secrets are plainly contrary to the legislative history. For example, discussion in the Subcommittee on [Agriculture] Department Investigation, Oversight and Research clearly shows specific recognition of all this data as trade secrets, see U.S. Code Congressional and Administrative News, 95th Congress, Second Session 1978, at pp. 2014-2015. See also House Conference Report, ibid., at pp. 2054-2056; Senate Report 95-334, at p. 31 (registrants' "proprietary interest" recognized). Equally invalid is appellant's argument that the use and/or disclosure is not a taking. The very essence of a trade secret is its confidentiality; dissemination destroys this primary characteristic thus depriving it of practically all value. St. Michael's Convalescent Hospital v. State of California, 643 F.2d 1369, 1374 (9th Cir. 1981); Wearly v. FTC, 462 F. Supp. 589 (D.N.J. 1978), vacated on other grounds 616 F.2d 662. Valuable rights have here been taken. Loretto v. Teleprompter Manhattan CATV Corp., 73 L.Ed.2d 868 (1982).

support deprivation of a citizen's property rights without payment of just compensation. The claimed economic goal of promoting competition and eliminating duplication are insufficient in this instance when (a) they are achieved by the forced sharing of appellee's property, and (b) they place the entire burden of such goals on appellee, to the obvious benefits accruing to the "me-too" registrants. Indeed, so obvious are those benefits that the Congress requires such "me-too" registrants to pay for them!! "If the government's encroachments on private property make it possible for another to get the benefits of that property, the United States is liable just as if it used the property for itself." Eyherabide v. U.S., 345 F.2d 565, 570 (Ct. Cl. 1965). It is the loss to the owner, not the accretion to the government, for which just compensation is to be made. See also Aris Gloves, Inc. v. U.S., 420 F.2d 1386 (Ct. Cl. 1970). Here, the statute requires the "me-too" registrants to make the payments, almost conclusive proof that it is a taking for private use - a clearly unconstitutional act.

The disclosure provisions are equally bizarre. The basis of their justification is a distrust of the federal agency's abilities. While the Congress certainly has the right to adopt appropriate and reasonable means necessary to accomplish its goals, it cannot place the entire burden and cost of compensating for the agency's deficiencies upon the submitting manufacturer. Ordinarily, when a federal agency has deficiencies, the Congress will take steps to correct them. Here, the steps taken are not addressed to meeting that problem. While this Court will properly refrain from trying to impose its own ideas of appropriate and reasonable means, it must still speak up when those means the Congress has chosen result in a taking beyond its constitutional powers. Surely there are appropriate

and reasonable means to curing an agency's deficiencies apart from taking the materials submitted to such agency, strewing them to the four winds and hoping that the person finding them will help the agency out.

Argument is here made of an "unconstitutional taking." Both words of this phrase should be focussed upon. We need look no further than the statute itself. It is clearly a "taking" if only because the statute itself provides for compensation to be made to the submitting manufacturer whose trade secrets are being used and/or disclosed.\* It is clearly "unconstitutional" if only because the statute itself provides that the compensation to be paid the submitting manufacturer is to be made by private parties, a conclusive indication it is for a private purpose, not the public use required by the Fifth Amendment. It would be difficult to conceive of a more patent "unconstitutional taking." But even if not unconstitutional, it is still a taking for which just compensation must be made.

<sup>\*</sup>The Congress clearly recognized appellee's property rights in the health and safety data, Senate Report 95-334, at p. 31. ("The amendments in S. 1678 recognize the proprietary interest in health and safety data on the part of pesticide registrants who underwrite the expense of obtaining such data.") In view of this it is somewhat difficult to understand appellant's extensive argument against recognizing this data as property which is taken.

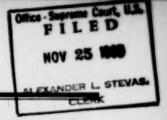
### CONCLUSION

For the reasons and authorities cited above, the judgment of the district court should be affirmed.

Respectfully submitted,

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As Amicus Curiae



IN THE

## Supreme Court of the United States

OCTOBER TERM, 1983

WILLIAM D. RUCKELSHAUS, ADMINISTRATOR,
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY,
Appellant,

MONSANTO COMPANY

On Appeal from the United States District Court for the Eastern District of Missouri

BRIEF OF THE
PESTICIDE PRODUCERS ASSOCIATION,
DREXEL CHEMICAL COMPANY,
FALLS CHEMICALS, INC., AND
GRIFFIN CORPORATION
AS AMICI CURIAE

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November 25, 1983

### TABLE OF CONTENTS

		Page
INTE	REST OF AMICI CURIAE	1
SUM	MARY OF ARGUMENT	4
ARGI	UMENT	6
I.	THE FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT, AS AMENDED, PROTECTS THE ENVIRONMENT FROM UNSAFE AND INEFFECTIVE PESTICIDES WHILE PROMOTING COMPETITION AND INNOVATION	6
	A. Congress Developed a Carefully Balanced Regulatory Scheme to Eliminate Wasteful Duplication of Testing and Minimize Regula- tory Barriers to Market Entry While Re- warding Innovation	7
	B. Experience Confirms That the Goals of the Act Have Been Achieved, But They Will Be Undone if the Act Is Held to Effect an Unconstitutional Taking	11
II.	EPA'S USE OF DATA SUBMITTED BY ONE REGISTRANT TO ESTABLISH THE SAFE-TY AND EFFICACY OF A SECOND APPLICANT'S PRODUCT DOES NOT CONSTITUTE A "TAKING"	16
III.	BECAUSE THE CONSTITUTIONALITY OF THE STATUTORY ARBITRATION SCHEME IS NOT RIPE FOR ADJUDICATION IN THIS LAWSUIT, THE DISTRICT COURT SHOULD BE DIRECTED TO DISMISS THE COM- PLAINT	23
CONC	CLUSION	25

### TABLE OF AUTHORITIES

A	SES:	Page
	Almeida-Sanchez v. United States, 413 U.S. 266	
	(1973)	18
	Amchem Products, Inc. v. GAF Corp., 594 F.2d 470 (5th Cir.), modified on other grounds, 602	
	F.2d 724 (5th Cir. 1979)	7
	Andrus v. Allard, 444 U.S. 51 (1979)  Babbitt v. United Farm Workers National Union, 442 U.S. 289 (1979)	22, 23 25
	Berman v. Parker, 348 U.S. 26 (1954)	
	Chevron Chemical Co. v. Costle, 499 F. Supp. 732 (D. Del. 1980), aff'd on other grounds, 641 F.2d	17, 21
	104 (3d Cir.), cert. denied, 452 U.S. 961 (1981) Chevron Chemical Co. v. Costle, 641 F.2d 104 (3d	19
	Cir.), cert. denied, 452 U.S. 961 (1981)6, 7, 8	, 9, 10,
		18, 19
	Ferguson v. Skrupa, 372 U.S. 726 (1963)	17
	Hancock v. Train, 426 U.S. 167 (1976)	18
	Hodel v. Indiana, 452 U.S. 314 (1981)	
	Loretto v. Teleprompter Manhattan CATV Corp., 458 U.S. 419 (1982)	17
	Mobay Chemical Corp. v. Costle, 517 F. Supp. 252 (W.D. Pa. 1981), aff'd sub nom. Mobay Chemical Corp. v. Gorsuch, 682 F.2d 419 (3d Cir.), cert. denied, 459 U.S. —, 103 S. Ct. 343	.,
	(1982)	7
	Cas. (BNA) 1572 (W.D. Mo. 1978), appeal dismissed for want of jurisdiction, 439 U.S. 320	
	(1979)	7, 9
	Northern Pacific Railway v. United States, 356 U.S. 1 (1958)	20
	Penn Central Transportation Co. v. New York	
	City, 438 U.S. 104 (1978)	, 22,23
	1981)	19
	83-1941 (D.D.C. filed July 7, 1983)	24
	74 (1980)	22, 23

TABLE OF AUTHORITIES—Continued	
	Page
Thompson v. Consolidated Gas Utilities Corp., 300 U.S. 55 (1937)	21
Union Carbide Agricultural Products Co. v. Costle, 632 F.2d 1014 (2d Cir. 1980), cert. denied, 450	7 10
U.S. 996 (1981)  United States v. Generix Drug Corp., 460 U.S.  —, 103 S. Ct. 1298 (1983)	7, 19
United States v. Topco Associates, Inc., 405 U.S. 596 (1972)	20
Usery v. Turner Elkhorn Mining Co., 428 U.S. 1 (1976)	17
STATUTES AND REGULATIONS:	
Federal Environmental Pesticide Control Act of 1972, Pub. L. No. 92-516, 86 Stat. 973	
section 3(c) (1) (D)	
section 10(a)section 10(b)	8
Federal Food, Drug, and Cosmetic Act of 1938, as amended, 21 U.S.C. §§ 301-92 (1976 & Supp. V 1981)	
section 301(j), 21 U.S.C. § 331(j)section 505(b), 21 U.S.C. § 355(b)	18 11
Federal Insecticide, Fungicide, and Rodenticide	
Act of 1947, c. 125, 61 Stat. 163	7
Stat. 751	9
Act, as amended, 7 U.S.C. §§ 136a-136y (1982)	3
section 3(c) (1) (D), 7 U.S.C. § 136a(c) (1) (D)	16, 19
section 3(c) (1) (D) (ii), 7 U.S.C. § 136a(c)	00 04
(1) (D) (ii)section 10, 7 U.S.C. § 136h	23, 24
Federal Pesticide Act of 1978, Pub. L. No. 95-396,	
92 Stat. 819	9
section 2	10
section 15	10

	TABLE OF AUTHORITIES—Continued	
		Page
	Insecticide Act of 1910, c. 191, 36 Stat. 335	6
	Toxic Substances Control Act, Pub. L. No. 94-469,	
	90 Stat. 2006, 15 U.S.C. §§ 2603-29 (1982)	11
	section 4(a), 15 U.S.C. § 2603(a)	11
	section 4(c) (2) (B), 15 U.S.C. § 2603(c) (2) (B)	11
	section 4(c)(3)(A), 15 U.S.C. § 2603(c)(3)	
	(A)	11
	Trade Secrets Act, 18 U.S.C. § 1905 (1982)	8, 18
	21 C.F.R. § 314.1 (1983)	11
LE	GISLATIVE MATERIALS:	
	H.R. REP. No. 663, 95th Cong., 1st Sess. (1977), reprinted in 1978 U.S. Code Cong. & Ad. News	
	1988	10
	S. REP. No. 838, pt. 2, 92d Cong., 2d Sess., re- printed in 1972 U.S. Code Cong. & Ad. News	
	3993	7
	S. REP. No. 970, 92d Cong., 2d Sess., reprinted in	
	1972 U.S. CODE CONG. & AD. NEWS 4092	8, 20
	1976 U.S. CODE CONG. & AD. NEWS 4491	11
	S. Rep. No. 334, 95th Cong., 1st Sess. (1977)	10
	124 Cong. Rec. S15303 (daily ed. Sept. 18, 1978)	10
MIS	SCELLANEOUS:	
	EPA, Office of Pesticide Programs, Agricultural	
	Impact Analysis of Chlorothalonil (Sept. 28,	
	1983)	12, 13
	EPA, OFFICE OF PESTICIDE PROGRAMS, FIFRA: IM- PACT ON THE INDUSTRY, reprinted in S. REP. No.	
	334, 95th Cong., 1st Sess. (1977)	7
	EPA, OFFICE OF RESEARCH & DEVELOPMENT, GUIDE-	
	LINE FOR THE DISPOSAL OF SMALL QUANTITIES	
	OF UNUSED PESTICIDES (1975)	14
	EPA, REGULATORY IMPACT ANALYSIS: DATA RE-	
	QUIREMENTS FOR REGISTERING PESTICIDES UNDER THE FEDERAL INSECTICIDE, FUNGICIDE, AND RO-	2
	DENTICIDE ACT (1982)	3

TABLE OF AUTHORITIES—Continued	
	Page
McGarity & Shapiro, The Trade Secret Status of Health and Safety Testing Information: Re-	
forming Agency Disclosure Policies, 93 HARV. L. REV. 837 (1980)	20
Plaintiffs' Proposed Judgment and Order (filed Oct. 5, 1983), Union Carbide Agricultural Products Co. v. Ruckelshaus, 19 Env't Rep. Cas. (BNA)	
1650 (S.D.N.Y. 1983)	14

### IN THE Supreme Court of the United States

OCTOBER TERM, 1983

No. 83-196

WILLIAM D. RUCKELSHAUS, ADMINISTRATOR,
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY,
Appellant,

MONSANTO COMPANY

On Appeal from the United States District Court for the Eastern District of Missouri

BRIEF OF THE
PESTICIDE PRODUCERS ASSOCIATION,
DREXEL CHEMICAL COMPANY,
FALLS CHEMICALS, INC., AND
GRIFFIN CORPORATION
AS AMICI CURIAE

### INTEREST OF AMICI CURIAE

The Pesticide Producers Association ("PPA") is a voluntary nonprofit group of approximately forty companies engaged primarily in producing, formulating and distributing agricultural pesticides in the United States. Members of PPA provide a direct link to the American farmer. In contrast to larger domestic and international companies, PPA members generally serve local and regional markets. Three of its member companies (Drexel Chemical Company, Falls Chemicals, Inc. and

Griffin Corporation) join with PPA in filing this brief to illustrate the drastic impact that affirmance of the decision below would have on PPA member companies and other small pesticide companies, the American farmer and the consuming public. Both parties to this case have consented to the filing of this brief; letters so indicating are filed herewith.

Drexel Chemical Company is a privately-held Tennessee corporation based in Memphis, Tennessee. Drexel does business primarily in the central and southeastern United States and has annual domestic sales of approximately \$25 million. Its principal pesticide products are atrazine, dinitro and methyl parathion, used on a variety of crops including corn, beans, and fruit crops. Over 75% of Drexel's revenues are derived from products registered under the regulatory scheme invalidated by the district court in this case, and more than thirty applications filed by Drexel under the scheme are pending with the Environmental Protection Agency ("EPA").

Falls Chemicals, Inc. is a privately-held Montana corporation headquartered in Great Falls, Montana. It sells its products in nine western states and has annual sales of approximately \$2 million. The company specializes in herbicides made with 2, 4-dichlorophenoxyacetic acid and/or 2-methyl-4-chlorophenoxyacetic acid, which are used mainly on grain crops such as corn, wheat and oats. These and all its other products have been registered with EPA under the statutory scheme invalidated by the district court.

Griffin Corporation is a privately-held Georgia corporation headquartered in Valdosta, Georgia, with additional manufacturing facilities in Texas. Its products are sold primarily in California, Florida and Georgia. Griffin's annual sales volume is less than \$50 million, about 65% of which derives from the sale of products, such as linuron, which are registered under the invali-

dated scheme. It, too, has several registration applications pending with EPA.

Until struck down by the court below, the pesticide registration scheme established by the Federal Insecticide. Fungicide, and Rodenticide Act. as amended, 7 U.S.C. §§ 136a-136y (1982) ("FIFRA"), assured competition in the pesticide industry by enabling PPA's member companies and other small pesticide marketers to obtain product registrations without the burdens and delays involved in having to assemble individually the costly and duplicative health and safety data on which registrations are based.1 Significantly, the scheme did not give one pesticide marketer access to the data produced by another company, or to another's product formulas or manufacturing processes. It simply permitted the agency to use information in its own files to determine that a subsequent applicant's product was safe and effective and hence eligible for registration.

Thousands of "follow-on" (also known as "me-too") pesticide products have been registered under this scheme, and thousands more are expected to be granted if the Court upholds the statute. However, if the Court affirms the district court's conclusion that the Fifth Amendment denies Congress the power to adopt this regulatory scheme, almost every small pesticide formulator and producer is likely to be forced out of the market. This result is diametrically contrary to Congress' assessment of the public interest. Even as to those few companies that might be able to afford the testing needed to support a registration, requiring them to do so will waste

<sup>&</sup>lt;sup>1</sup> EPA recently found that the 1980-81 cost of the testing necessary to support a registration was approximately \$1.9 million to \$2.8 million per active ingredient. See EPA, REGULATORY IMPACT ANALYSIS: DATA REQUIREMENTS FOR REGISTERING PESTICIDES UNDER THE FEDERAL INSECTICIDE, FUNGICIDE AND RODENTICIDE ACT 14-15, 70, 72 (1982). PPA members' experience shows that these figures may be understated.

scarce scientific resources and millions of dollars, again in conflict with Congress' perception of the public interest.

The parties' briefs undoubtedly will address fully the profound constitutional issues presented by this case. In filing this brief as amici curiae, our principal aim is not to duplicate those arguments, but to describe the practical ramifications of invalidating the key registration provisions of FIFRA. As we shall show, a decision that the Constitution requires each applicant for a pesticide registration to assemble health and safety data—even if it duplicates data already in EPA's files on the same product—is likely to cause the demise of a significant portion of the American pesticide industry.

#### SUMMARY OF ARGUMENT

I.

Relying primarily on legal principles of a bygone constitutional era, the district court struck down the heart of the pesticide regulatory scheme fashioned by Congress in the 1970s. That scheme embodies four basic objectives: (1) to assure the public that all pesticides sold in the United States are effective and will not unreasonably harm the environment; (2) to streamline the regulatory process to eliminate waste and duplication of effort: (3) to minimize possible disincentives to innovation by spreading the cost of assembling data among all registrants that benefit from the data; and (4) to minimize the barriers to market entry resulting from regulatory requirements and eliminate the de facto extension of patent protection that otherwise would result. Congress grappled with balancing these goals for over six years, and concluded that they could best be achieved by authorizing EPA to conclude that pesticide products are safe and effective on the basis of health and safety data already placed in the Agency's files by registrants of

equivalent products, as long as the subsequent registrants agree to share the cost of producing the data.

Congress' judgment of how best to serve these public purposes has proven correct. The record since this statutory scheme was adopted reveals substantially increased competition in the pesticide market, resulting in lower prices to the farmer and ultimately to the consumer; a more efficient regulatory process; and adequate incentives to product innovation. If the Court affirms the decision below and invalidates the follow-on scheme, however, the additional funds that each registrant will be required to spend to comply with FIFRA's testing requirements for future registrations will be so substantial that virtually no small pesticide company will remain a viable force in this industry. This result will be compounded if existing follow-on registrations are voided, as urged by several companies that originally submitted the data on which those registrations are based. Affirmance of the decision below thus would totally eviscerate the pesticide registration scheme Congress designed to serve the public interest.

#### II.

Contrary to the view of the district court, nothing in the Fifth Amendment compels the calamitous results described above. In holding that FIFRA unconstitutionally effected a taking of Monsanto's property, the district court misapplied the principles of Penn Central Transportation Co. v. New York City, 438 U.S. 104 (1978), by overstating the nature of Monsanto's property interest in data it had voluntarily turned over to EPA and disregarding the manifest public purposes of the Act.

#### III.

In addition to striking down FIFRA's follow-on registration scheme, the district court held the Act's arbitration provision unconstitutional because it purportedly

does not afford just compensation to remedy the Fifth Amendment "taking." However, if there is no "taking," there is no requirement for just compensation and no need to decide whether the arbitration scheme affords it. Moreover, the decision below on the constitutionality of the arbitration provision was premature because Monsanto has not invoked the arbitration mechanism to resolve a compensation dispute with a follow-on registrant and it is speculative whether it ever will. Accordingly, regardless of how this Court resolves the "taking" question, it should reverse the judgment concerning the arbitration scheme and, to that extent, direct the district court to dismiss the complaint.

### ARGUMENT

I. THE FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT, AS AMENDED, PROTECTS THE ENVIRONMENT FROM UNSAFE AND INEFFECTIVE PESTICIDES WHILE PROMOTING COMPETITION AND INNOVATION.

Congress has regulated the sale of agricultural fungicides and pesticides in interstate commerce for nearly seventy-five years. See Chevron Chemical Co. v. Costle, 641 F.2d 104, 106 (3d Cir.), cert. denied, 452 U.S. 961 (1981) (citing Insecticide Act of 1910, c. 191, 36 Stat. 335). In the 1970s, Congress undertook, in three successive sets of amendments, to achieve the appropriate balance between several competing interests while assuring the safety and efficacy of pesticides vital to the nation's farm economy. In this section of the brief, we review Congress' effort to grapple with these issues, then demonstrate that the legislation has accomplished precisely what Congress intended and describe the devastating impact of striking it down.

A. Congress Developed a Carefully Balanced Regulatory Scheme to Eliminate Wasteful Duplication of Testing and Minimize Regulatory Barriers to Market Entry While Rewarding Innovation.

Congress first required registration of pesticide products as a precondition for their sale in interstate commerce in 1947. To obtain such a registration, the applicant was required to submit test data showing that the product was safe and effective. FIFRA §§ 2-13, 61 Stat. 163-7° (1947).

U. 1972, the registration agency used information in its files already provided by a prior registrant in approving follow-on registration applications without obtaining permission from the original data submitter, but did not disclose the information to later applicants.<sup>2</sup> In 1972, responding to several concerns, including that follow-on applicants could obtain an unfair cost advantage over those companies that undertook the required testing and that the existing system provided disincentives for innovation, Congress amended the statute. As modified, FIFRA directed that if the agency used information previously submitted by one registrant to approve a second company's follow-on application, the follow-on applicant must first offer to pay "reasonable compensation" to the initial registrant. FIFRA § 3 (c)

<sup>&</sup>lt;sup>2</sup> See Chevron Chem. Co. v. Costle, 641 F.2d at 109 (citing EPA, OFFICE OF PESTICIDE PROGRAMS, FIFRA: IMPACT ON THE INDUSTRY, reprinted in S. REP. No. 334, 95th Cong., 1st Sess. 34 (1977)); Union Carbide Agric. Prods. Co. v. Costle, 632 F.2d 1014, 1016 (2d Cir. 1980), cert. denied, 450 U.S. 996 (1981); Amchem Prods., Inc. v. GAF Corp., 594 F.2d 470, 472 (5th Cir.), modified on other grounds, 602 F.2d 724 (5th Cir. 1979); Mobay Chem. Corp. v. Costle, 517 F. Supp. 252, 267 n.11 (W.D. Pa. 1981), aff'd sub nom. Mobay Chem. Corp. v. Gorsuch, 682 F.2d 419 (3d Cir.), cert. denied, 459 U.S. —, 103 S. Ct. 343 (1982); Mobay Chem. Corp. v. Costle, 12 Env't Rep. Cas. (BNA) 1572, 1580 n.22 (W.D. Mo. 1978), appeal dismissed for want of jurisdiction, 439 U.S. 320 (1979); S. Rep. No. 838, pt. 2, 92d Cong., 2d Sess. 18-19, reprinted in 1972 U.S. Code Cong. & Ad. News 3993, 4040.

(1) (D), Pub. L. No. 92-516, 86 Stat. 979 (1972). See Chevron Chemical Co. v. Costle, 641 F.2d at 107. Congress also added new provisions to the statute designed to protect prior registrants' trade secrets. Significantly, however, Congress refused to give data submitters the right to exclusive use of their own data. It thus evidenced concern that an exclusive use scheme would confer anticompetitive, quasi-patent privileges on registered products, even after their patents had expired or where the product consisted of unpatentable common chemicals in the public domain.

However, the 1972 amendments did not achieve Congress' aims. Because FIFRA contained no definition of the term "trade secrets," the 1972 amendments, in effect, gave data submitters unrestricted authority to label any portion of their data submissions as trade secret material and to bind the agency to that characterization.

<sup>&</sup>lt;sup>3</sup> Section 10(a) of the 1972 Act, Pub. L. No. 92-516, 86 Stat. 989, permitted an applicant to designate portions of the data as trade secrets, while section 10(b) prohibited the agency from disclosing material designated as trade secrets under section 10(a) except as necessary to carry out its statutory duties. The Trade Secrets Act, 18 U.S.C. § 1905 (1982), also prohibited government officials from disclosing trade secrets to the public.

<sup>&</sup>lt;sup>4</sup> Congress repeatedly expressed concern that the registration system could extend patent monopolies beyond those authorized by the patent system. The Senate Committee on Commerce deleted an "exclusive use" provision in the 1972 bill because

barriers to entry in the pesticides industry would result which go far beyond that envisioned by our patent system. In effect, whether or not a pesticide has patent protection, a manufacturer wishing to register a pesticide previously registered would have to duplicate the required test data . . . In the extreme, a monopoly in the production of a pesticide could ensue if competitors are unable to afford the sometimes costly safety and efficacy tests.

REP. No. 970, 92d Cong., 2d Sess. 12, reprinted in 1972 U.S. Code
 Cong. & Ad. News 4092, 4096. See also id. at 14, 16, reprinted in
 1972 U.S. Code Cong. & Ad. News at 4098, 4100.

Furthermore, because section 3(c)(1)(D) also prohibited the agency from relying on data labelled by the submitter as a "trade secret," the practical utility of the data reliance scheme was severely limited.

Congress sought to narrow the competitive restrictions established in the 1972 amendments when it again amended the statute in 1975. Pub. L. No. 94-140, 89 Stat. 751. Among other modifications, Congress expressly eliminated any compensation requirements for reliance on data submitted before 1970, and required payment of such compensation only from applicants whose registration applications were filed after October 21, 1972. 89 Stat. 755 (1975).

Despite Congress' intentions, the overall effect of the 1972 and 1975 amendments was an "administrative nightmare in which the process of registering new pesticides simply ground to a halt." Chevron Chemical Co. v. Costle, 641 F.2d at 111. This proved to be a complete bar to new market entry. Id. Congress thus again revisited the regulatory scheme in 1978. Pub. L. No. 95-396, 92 Stat. 819.

<sup>&</sup>lt;sup>5</sup> This amendment left in place the agency's prior practice of using pre-1970 data in its files to determine the safety and efficacy of products covered by follow-on applications without compensating the initial registrant, and also the provision that barred the agency from relying on data submitted after 1970 designated under section 10(a) by the submitter as a trade secret.

The constitutionality of this data reliance program was upheld by a three-judge district court in Mobay Chem. Corp. v. Costle, 12 Env't Rep. Cas. (BNA) 1572 (W.D. Mo. 1978). A direct appeal to this Court was dismissed because the Court concluded that a three-judge court had been improperly convened. Mobay Chem. Corp. v. Costle, 439 U.S. 320 (1979) (per curiam). Justice Blackmun concluded in dissent, however, that the agency's practice of using such data for follow-on applications without compensation was ratified by Congress in the 1975 amendments and that the three-judge court accordingly had been properly convened. Based on this reasoning, he believed that this Court had jurisdiction over the appeal. On the merits, he concluded that the district court had correctly upheld the constitutionality of the practice. Id. at 321.

In response to strong complaints from EPA, the Department of Justice, and others about the ineffectiveness of the 1972 and 1975 amendments in promoting competition, further amendments to section 3(c)(1)(D) were adopted.6 Congress reaffirmed the agency's right to use data in its files for follow-on registrations, subject to an arbitration procedure to resolve disputes over compensation; limited the time period during which data used in support of a follow-on application require compensation: and repealed the statutory prohibition that had barred the agency from disclosing or relying on data that the submitter had labelled as "trade secret" information. Id. §§ 2, 15 (codified at 7 U.S.C. §§ 136a(c)(1)(D), 136h (1982)). In addition, to reward innovation, Congress granted the submitter a ten-year period of exclusive use for data involving new active ingredients or new uses of previously registered products. Id. § 2, 7 U.S.C. § 136a (c) (1) (D): see Chevron Chemical Co. v. Costle, 641 F.2d at 113-14.

In short, the 1978 amendments reflected the coalescing of four important public objectives, each of which plainly falls within Congress' legislative power. First, the Act provides a regulatory mechanism intended to assure that only safe and effective pesticides are sold in interstate commerce. Second, by authorizing EPA to rely on data in its own files, Congress hoped to streamline the regulatory process, and thereby eliminate waste and duplication of effort. Third, by establishing a mechanism to compensate registrants whose data are used in approving followon registrations, Congress chose to spread the cost of assembling the data among all registrants that benefitted

<sup>&</sup>lt;sup>6</sup> See S. Rep. No. 334, 95th Cong., 1st Sess. 3, 8, 30-31 (1977) (indicating Congress' dissatisfaction with the effect of the data requirements as an extension of patents beyond the seventeen-year statutory period of protection). See also 124 Cong. Rec. S15303-04 (daily ed. Sept. 18, 1978) (remarks of Sen. Leahy); H.R. Rep. No. 663, 95th Cong., 1st Sess. 18 (1977), reprinted in 1978 U.S. Code Cong. & Ad. News 1988, 1991.

from the data. It thereby sought to minimize possible disincentives to innovation if initial registrants had to bear the entire cost of a registration application while potential competitors enjoyed a "free ride" on the initial registrant's costly studies. Finally, to minimize barriers to market entry resulting from the data submission requirements and thus promote competition, Congress reaffirmed the agency's right to use data in its files to approve follow-on applications for products the agency had already found to be safe and effective.

B. Experience Confirms That the Goals of the Act Have Been Achieved, But They Will Be Undone If the Act Is Held to Effect an Unconstitutional Taking.

The record since Congress last amended the statute in 1978 shows that it has accomplished what Congress set out to do. As Congress predicted, section 3(c)(1)(D)

<sup>7</sup> A scheme similar to FIFRA's data reliance scheme was adopted by Congress in 1976 to govern regulation of chemical substances and mixtures. See Toxic Substances Control Act ("TSCA"), Pub. L. No. 94-469, 90 Stat. 2006, 15 U.S.C. §§ 2603-29 (1982). That Act requires testing of certain potentially hazardous substances (TSCA § 4(a), 15 U.S.C. § 2603(a)), but exempts any firm whose product is equivalent to a substance for which data have been submitted and where testing would be duplicative (TSCA § 4(c) (2) (B), 15 U.S.C. § 2603(c)(2)(B)), if it pays "fair and equitable reimbursement" to the companies that sponsored the tests (TSCA § 4(c) (3) (A), 15 U.S.C. § 2603(c) (3) (A)). As in the case of FIFRA, Congress was concerned here with wasteful duplication and wished to avoid the anticompetitive effect of a scheme that required every firm to submit data, whether or not the substance of the data already was known to the Agency. See S. REP. No. 698, 94th Cong., 2d Sess. 12, 16, reprinted in 1976 U.S. Code Cong. & AD. NEWS 4491, 4502, 4506.

In contrast to FIFRA and TSCA, section 505(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(b) (1976), has been interpreted by FDA to require duplicative testing in connection with a new drug application. See 21 C.F.R. § 314.1 (1983). The Court considered a different aspect of this scheme last Term in United States v. Generix Drug Corp., 460 U.S. ——, 103 S. Ct. 1298 (1983).

has removed unnecessary barriers to market entry created by the Act's data submission requirement and has facilitated the emergence of a competitive market environment. EPA still must examine each proposed pesticide product to confirm its safety and efficacy, but it no longer must ignore pertinent information in its own files. Similarly, registration applicants for follow-on products no longer must conduct years of costly studies to prove again and again what the Agency already can determine from data in its files.

Most competition in this industry comes from follow-on products. For example, of approximately sixty companies that have a registration for a four pound per gallon methyl parathion product (including Monsanto), at least 90% (including all three individual amici) hold follow-on registrations. Similarly, of the dozen or so companies that market a three pound per gallon dinitro product, at least two-thirds (including Drexel) hold follow-on registrations.

The approval of a follow-on application can produce almost immediate economic benefits to farmers and the public in the form of reduced prices, often even before the follow-on product reaches the market. For instance, through 1983, the Diamond Shamrock Corporation, a multinational conglomerate with annual sales of over \$3 billion, has been the only registrant of technical chlorothalonil, a fungicide used on most of the American peanut crop, on soybeans and on various vegetables. Diamond Shamrock holds patents on chlorothalonil and hence has had no competition in the sale of that product." Because these patents are about to expire, Griffin Corporation obtained a registration for technical chlorothalonil in January 1983. Until that time, Diamond Shamrock's product sold for approximately \$23 per gallon wholesale. However, shortly after Griffin received its registration.

<sup>\*</sup> EPA, Office of Pesticide Programs, Agricultural Impact Analysis of Chlorothalonil at 5 (Sept. 28, 1983).

Diamond Shamrock dropped its price to \$18 per gallon, without even waiting for Griffin to begin marketing the product. This price reduction alone will save American farmers millions of dollars per year.

The price for atrazine, which is used on approximately sixty-four million acres of crops in this country, also has dropped since follow-on registrations have been issued. In 1976, before the patent held by Ciba-Geigy Corporation expired, the wholesale price was approximately \$13 per gallon. Since then, at least eight follow-on registrations have been issued (including to Griffin and Drexel), and the current price is approximately \$7 per gallon. With approximately twenty million pounds of atrazine used each year, this price reduction has yielded enormous cost savings for this country's farmers.

A similar price reduction is likely in the domestic trifluralin market by 1985 when that patent, held by an Eli Lilly Company subsidiary, expires. This pesticide is used in the United States primarily on cotton and soybeans and also is sold abroad. In the United States, trifluralin is sold to distributors for approximately \$28 to \$30 per gallon (assuming a formulation of four pounds per gallon), while the price abroad, where multiple sellers compete with each other, is less than half the domestic price. Drexel Chemical Company already has received a trifluralin follow-on registration from EPA and expects to begin marketing the product in 1985 as soon as Eli Lilly's patent expires. The domestic price can be expected to drop substantially at that time, and the impact of this decrease will be widespread. PPA members' market evaluations show that in 1982 alone, approximately fifty-

<sup>9</sup> Id. at 9. As EPA recognizes, price decreases are likely when a pesticide company suddenly faces competition, after having been "isolated...by patent or other similar protection." Id.

three million pounds of trifluralin were produced in the United States. 10

If the Court affirms the decision below and invalidates the follow-on scheme, there appears to be no question that many initial registrants will seek to cancel existing follow-on registrations. For example, both Drexel Chemical Company and Griffin Corporation recently have received letters from the du Pont Company, the initial registrant of linuron, a pesticide for which both amici hold follow-on registrations, stating that du Pont intends to seek to nullify those registrations.11 More generally, plaintiffs (including Monsanto) in a case pending in the Southern District of New York in which the FIFRA arbitration scheme has been found unconstitutional have urged that court to cancel all post-1978 follow-on registrations as well as to enjoin all future registrations under section 3(c) (1) (D). See Plaintiffs' Proposed Judgment and Order, ¶¶ 2, 3 (filed Oct. 5, 1983), Union Carbide Agricultural Products Co. v. Ruckelshaus, 19 Env't Rep. Cas. (BNA) 1650 (S.D.N.Y. 1983).

In the face of such cancellations, only one option would remain for current follow-on registrants which wish to compete vigorously with the initial registrant: to duplicate and submit to EPA data already in the files. This would not, however, be economically feasible. Most of Drexel Chemical Company's principal pesticide products, for example, have follow-on registrations issued since

<sup>&</sup>lt;sup>10</sup> See also EPA, OFFICE OF RESEARCH & DEVELOPMENT, GUIDELINE FOR THE DISPOSAL OF SMALL QUANTITIES OF UNUSED PESTICIDES at 161, table C (1975) (the atrazine production volume in the United States in 1971 was 25 million pounds).

<sup>&</sup>lt;sup>11</sup> See Letters from Louis Del Vecchio, Legal Department, du Pont de Nemours & Company, to Michael T. Smith, Vice-President, Drexel Chemical Company, and John D. Elliot, Vice-President, Griffin Corporation, Nov. 8, 1983.

1978. If the company now were required to spend approximately \$1.8 to \$2.9 million per active ingredient to generate its own data,<sup>12</sup> it would have to spend as much as \$5.8 million, almost one-fourth the company's annual sales volume, to continue marketing its primary products.

Similarly, Drexel now has over twenty-five applications for follow-on registrations with different active ingredients pending at EPA, which cannot be processed because of the district court's injunction. The cost of testing for these products could reach \$72 million, almost three times Drexel's annual sales volume. Moreover, Drexel's circumstances are hardly unique. EPA estimated in its application to Justice Blackmun to stay the judgment below that over the course of a year, applications for 1,700 to 2,200 new products will be precluded or delayed because of the district court's decision.<sup>13</sup>

Furthermore, these are not tests that can be duplicated overnight; many are extremely time consuming, including some that will take as long as four years to complete.<sup>14</sup> This delay in obtaining registrations will handicap the smaller companies seeking to return to the market because of the substantial headstart gained by the few large firms that already have received registrations based on their own data. EPA estimates that less than 25% of the anticipated registration applications for new agricultural pesticides or amendments thereto are likely to qualify for registration if the data reliance scheme were invalidated.<sup>15</sup>

<sup>12</sup> See note 1 supra.

<sup>&</sup>lt;sup>13</sup> Affidavit of Edwin L. Johnson, Director, EPA Office of Pesticide Programs, submitted in support of EPA's Application for a Stay of Judgment of the United States District Court for the Eastern District of Missouri Pending Direct Appeal, July 1983, § 6.

<sup>14</sup> Id. 1 5.

<sup>18</sup> Id. 16.

Finally, sharp price increases are almost certain to follow a decision that results in the cancellation of existing follow-on registrations. This will occur in two ways. First, registrants who have submitted data, no longer facing competition from follow-on sellers, will be able to raise their prices with impunity. Second, even if some of the small pesticide firms can afford to sponsor their own tests and eventually return to the market, the cost of market entry will be substantially higher than at present, forcing them to set their own prices at significantly higher levels than they do today.

In sum, the sharp decline in competition that inevitably would follow invalidation of the 1978 amendments would affect not only the viability of most small pesticide companies, but also, in turn, would increase the costs of American farmers and the prices they charge for their products. As we show in Section II of this brief, nothing in the Fifth Amendment compels such a calamitous result. To the contrary, Congress enacted section 3(c) (1) (D) of FIFRA under its broad Commerce Clause authority to prevent such consequences, and plainly the legislation has accomplished what Congress intended.

II. EPA'S USE OF DATA SUBMITTED BY ONE REGISTRANT TO ESTABLISH THE SAFETY AND EFFICACY OF A SECOND APPLICANT'S PRODUCT DOES NOT CONSTITUTE A "TAKING."

In holding that FIFRA unconstitutionally effected a taking of Monsanto's property, the district court rejected at least a half century of modern jurisprudence confirming the full breadth and scope of Congress' authority to

<sup>&</sup>lt;sup>16</sup> For example, in today's market, over 40 million pounds of 2, 4-dichlorophenoxyacetic acid are applied annually on grain crops such as corn, wheat, barley, rye and oats, and some two dozen firms, including Falls Chemicals, hold follow-on registrations. If these firms are forced out of the market because their follow-on registrations have been cancelled, the data submitters for those products will be free to raise their prices substantially.

enact "public program[s] adjusting the benefits and burdens of economic life to promote the common good" 17 and sharply limiting the judicial reexamination of the purpose for which Congress has exercised its legislative power.18 More specifically, the district court applied the Takings Clause in a wooden and impractical manner that totally disregards the balancing approach called for by this Court's decision in Penn Central Transportation Co. v. New York City, 438 U.S. 104, 130-31 (1978) (the Court must examine "the character of the action . . . [and] the nature and extent of the interference with rights in the [property] as a whole"). See also Loretto v. Teleprompter Manhattan CATV Corp., 458 U.S. 419, 432 (1982). Its conclusion that this scheme effects an unconstitutional taking rests largely on its failure to appreciate the fact that, as described above, this scheme serves important public interests that Congress was entitled to promote. See, e.g., Berman v. Parker, 348 U.S. 26, 32-33 (1954).

A. As a threshold matter, and as the Third Circuit has held (see Chevron Chemical Co. v. Costle, 641 F.2d 104, 114-16, cert. denied, 452 U.S. 961 (1981)), the district court overstated the nature of Monsanto's property interest. One can assume that so long as the data remained entirely in Monsanto's possession they were

<sup>&</sup>lt;sup>17</sup> Penn Central Transp. Co. v. New York City, 438 U.S. 104, 124 (1978); see Usery v. Turner Elkhorn Mining Co., 428 U.S. 1, 15 (1976).

<sup>18</sup> See, e.g., Hodel v. Indiana, 452 U.S. 314, 323-24 (1981) ("court may invalidate legislation enacted under the Commerce Clause only if it is clear that there is no rational basis for a congressional finding... that there is no reasonable connection between the regulatory means selected and the asserted ends"); Ferguson v. Skrupa, 372 U.S. 726, 729 (1963) ("[u]nder the system of government created by our Constitution, it is up to legislatures, not courts, to decide on the wisdom and utility of legislation"); Berman v. Parker, 348 U.S. 26, 32 (1954) ("role of the judiciary in determining whether [the taking] power is being exercised for a public purpose is an extremely narrow one").

treated as trade secrets entitled to some form of legal protection. But Monsanto generated the data to receive a regulatory benefit, and consistent with that purpose, chose to apply for a registration which necessarily involved disclosure of the data to EPA. In such a circumstance, Monsanto has no constitutional right to set the terms under which it turns information over to a government agency. By voluntarily availing itself of the benefits of the pesticide registration program, Monsanto acquiesced in "the burdens as well as the benefits" of the program. Almeida-Sanchez v. United States, 413 U.S. 266, 271 (1973); see Chevron Chemical Co. v. Costle, 641 F.2d at 115-16.

The district court's decision also has disturbing implications concerning federal/state relationships. Federal agencies receive data from private sources virtually every day. These agencies' operations easily could be hamstrung if their use of such data were restricted by state intellectual property laws. Regardless of whether the district court has correctly construed Missouri's trade secret law, reliance on state law to restrict the federal government's use of data in its own files is incompatible with the principle of the Supremacy Clause that "shield[s] federal installations and activities from regulation by the States." Hancock v. Train, 426 U.S. 167, 179 (1976). See also Chevron Chemical Corp. v. Costle, 641 F.2d at 116.20

<sup>&</sup>lt;sup>19</sup> While Congress obviously may accord protection to a private entity's voluntary data submission (see, e.g., Trade Secrets Act, 18 U.S.C. § 1905 (1982); Federal Food, Drug, and Cosmetic Act § 301(j), 21 U.S.C. § 331(j) (Supp. V 1981)), the Constitution does not require it to do so.

<sup>&</sup>lt;sup>20</sup> In relying on state trade secret law, the district court appeared to confuse internal use of agency data containing a private entity's trade secrets with public disclosure. As the Third Circuit pointed out in *Chevron*, neither state trade secret laws nor the federal Trade Secrets Act has anything to do with internal use. 641 F.2d at 115-16.

B. Even positing that data in EPA's files are the data submitter's "property" protected by the Fifth Amendment, the district court was flatly in error when it held that section 3(c)(1)(D) "unabashedly operates to further a private purpose." J.S. App. at 32a. In reaching this conclusion, the district court ignored the contrary conclusion of every other court that has addressed this issue. viz., that FIFRA's data reliance provision promotes substantial public purposes. See Chevron Chemical Co. v. Costle, 641 F.2d 104, 116 (3d Cir. 1981), aff'g 499 F. Supp. 732, 740-42 (D. Del. 1980), cert, denied, 452 U.S. 961 (1981); Petrolite Corp. v. EPA, 519 F. Supp. 966. 974 (D.D.C. 1981). See also Union Carbide Agricultural Products Co. v. Costle, 632 F.2d 1014, 1018 (2d Cir. 1980), cert. denied, 450 U.S. 996 (1981) (denying a preliminary injunction to enjoin use of section 3(c)(1) (D)).

The correct view, demonstrated by these several decisions rejected by the court below, is supported by a number of facts. Most fundamentally, Congress' legislative authority under the Commerce Clause amply supports a regulatory scheme that conditions the right of a pesticide producer to market a product on submission of data to the government that establish that the product is safe and effective. There is no jeopardy to public health and safety in allowing EPA to rely on data already in its possession rather than requiring each applicant to generate its own test data, and this results in enormous savings of administrative costs and time spent in the registration process.

Furthermore, such a streamlined regulatory formula works to the benefit of all taxpayers as well as the applicants for registrations. A scheme that prohibited EPA from relying on data in its own files, thereby forcing each applicant to duplicate the health and safety data previously submitted, would waste scientific resources by diverting research and development expertise to unpro-

ductive uses.<sup>21</sup> The purpose of the statute is not to create a regulatory obstacle course that all pesticide marketers must complete to be eligible to market their products, but to erect a regulatory scheme that permits EPA to assure the public that all pesticides on the market are safe and effective. Because the purpose of the testing is to secure the information EPA needs to determine whether a pesticide is safe and effective, Congress plainly was entitled to fashion a regulatory scheme that provided EPA with that information without imposing on every applicant a makework assignment to duplicate and submit to the agency information it already possesses.

In addition, by minimizing the barriers to entry caused by the regulatory scheme, the data reliance scheme fosters competition. That competition is one of the most important of the nation's public policies <sup>22</sup> and that Congress has ample power to promote competition <sup>23</sup> need no longer be argued. Moreover, because the products involved in follow-on registrations are either common chemical compounds or products with expired or soon to expire patents and therefore can be sold lawfully by anyone (subject, of course, to prior registration under FIFRA), Congress was entitled to structure the pre-marketing data submission requirement to minimize any barriers to new market entry created by the regulatory scheme itself. Congress

<sup>&</sup>lt;sup>21</sup> See S. Rep. No. 970, 92d Cong., 2d Sess. 12-16, reprinted in 1972 U.S. Code Cong. & Ad. News 4092, 4096-100; McGarity & Shapiro, The Trade Secret Status of Health and Safety Testing Information: Reforming Agency Disclosure Policies, 93 HARV. L. Rev. 837, 845, 847 (1980).

<sup>&</sup>lt;sup>22</sup> See, e.g., United States v. Topco Assocs., Inc., 405 U.S. 596, 610 (1972) ("[a]ntitrust laws . . . are the Magna Carta of free enterprise"); Northern Pac. Ry. v. United States, 356 U.S. 1, 4 (1958) ("Sherman Act was designed to be a comprehensive charter of economic liberty aimed at preserving free and unfettered competition as the rule of trade").

<sup>22</sup> See, e.g., United States v. Topco Assocs., Inc., 405 U.S. at 611-

has no constitutional obligation to transform the data submission requirement in FIFRA into a vehicle extending to initial registrants the equivalent of an indefinite patent monopoly for unpatented products.<sup>24</sup>

The district court's finding that "the trial record amply demonstrates [that] competition [in] the pesticide industry [is] healthy and vibrant" (J.S. App. at 32a) misses the point. Competition in this industry is largely the product of the 1978 legislation. Congress was concerned with the non-competitive environment that prior law had created, and adopted a reasonable statutory provision designed to change the conditions that concerned it.<sup>25</sup>

In any case, it was not the district court's province to second-guess Congress' judgment about the state of competition in the pesticide industry or to determine whether Congress had mandated too much competition. That is precisely the type of legislative judgment reserved to Congress. See Hodel v. Indiana, 452 U.S. 314, 326 (1981). The role of the judiciary in such circumstances is "an extremely narrow one"; Congressional findings of public purpose are "well-nigh conclusive." Berman v. Parker, 348 U.S. 26, 32 (1954). Once the existence of a valid public purpose has been determined, the fact that some private benefit incidentally flows from the regulatory scheme becomes irrelevant. See id.; Thompson v. Consolidated Gas Utilities Corp., 300 U.S. 55, 77 (1937).

C. Given the district court's overstatement of Monsanto's property interest in the data and its failure to recognize the public purposes that underlie the regulatory action to which Monsanto objects, the conclusion that FIFRA effects an unconstitutional "taking" of Monsanto's property rests on an improper application of the principles described in Penn Central Transportation Co. v. New York City, 438 U.S. at 123-35. Moreover, in

<sup>24</sup> See note 4 supra and accompanying text.

<sup>25</sup> See pp. 9-11 supra.

that case, this Court pointed out that "[a] 'taking' may more readily be found when the interference with property can be characterized as a physical invasion by government . . . than when interference arises from some public program adjusting the benefits and burdens of economic life to promote the common good." *Id.* at 124. Here, to the extent there is any interference with property, we are concerned with interference resulting from a public program rather than a physical invasion of property.

The district court concluded that use of Monsanto's data in EPA's files to approve a competitor's registration deprived Monsanto of the ability to exclude its competitors from the market. J.S. App. at 31a. While it is true that the right to exclude others is one of the attributes of a property interest, that factor alone does not establish a "taking." See Pruneyard Shopping Center v. Robins, 447 U.S. 74, 82-83 (1980). Monsanto has "failed to demonstrate that the 'right to exclude others' is so essential to the use or economic value of [its] property" that EPA's use of the data to register follow-on products amounts to a "taking." Id. at 84. At most, it deprives Monsanto of one strand of a bundle of property rights. See Andrus v. Allard, 444 U.S. 51, 65-66 (1979). Monsanto still retains the use of the data for its own purposes, although, of course, its principal value has been to provide EPA with a basis for registering Monsanto's product. Monsanto's investment expectation in generating the data therefore was achieved when it received the registration from EPA and began marketing the registered product. See Penn Central Transportation Co. v. New York City, 438 U.S. at 136-38.

To be sure, if Monsanto retained exclusive use of its own data, that would delay and perhaps prevent competitors from entering the market. The effect would be to reduce the level of competition in the market and undoubtedly to increase Monsanto's profits. But "regulations [that] prevent the most profitable use of . . . prop-

erty" do not thereby effect a "taking." Andrus v. Allard, 444 U.S. at 66. "[L]oss of future profits—unaccompanied by any physical property restriction—provides a slender reed upon which to rest a taking claim." Id.

Finally, the mere fact that regulations "designed to promote the general welfare . . . burden some more than others" does not transform regulation into a "taking." See Penn Central Transportation Co. v. New York City, 438 U.S. at 113. Yet it also is significant that Monsanto and other initial registrants have not been singled out to bear all the burdens of the regulatory scheme while others enjoy its benefits. Monsanto benefits from the scheme by receiving a regulatory license to market its product with a de facto government testimonial that the product is safe and effective. Moreover, as noted above, the scheme seeks to mitigate the burdens on prior registrants whose data may be used in granting registrations to other applicants by spreading the cost of testing and assembling the data among all who benefit from the data. The fact that Congress formulated a scheme that avoids a disproportionate burden on any one segment of the industry indicates that any reduction in the value of Monsanto's property stems from regulation to promote the general welfare rather than from a "taking." See Pruneyard Shopping Center v. Robins, 447 U.S. at 82-83; Penn Central Transportation Co. v. New York City, 438 U.S. at 124-25.

III. BECAUSE THE CONSTITUTIONALITY OF THE STATUTORY ARBITRATION SCHEME IS NOT RIPE FOR ADJUDICATION IN THIS LAWSUIT, THE DISTRICT COURT SHOULD BE DIRECTED TO DISMISS THE COMPLAINT.

In addition to addressing FIFRA's follow-on registration scheme, the district court also concluded that the arbitration provision in section 3(c)(1)(D)(ii) is unconstitutional. It held that the arbitration scheme fails to meet constitutional requirements for affording just

compensation to remedy a Fifth Amendment "taking." <sup>26</sup> Absent a "taking," however, there is no requirement for just compensation. Therefore, if the district court's "taking" conclusion is rejected, the constitutionality of the arbitration remedy is not ripe for adjudication, and the proper disposition of this case is to reverse the district court's judgment in its entirety and to direct it to dismiss the complaint.

Even if this Court were to affirm the district court's taking conclusion, however, it still would be premature for any court hearing this lawsuit to determine whether the arbitration mechanism satisfies constitutional requirements for affording just compensation. Monsanto has not invoked the arbitration mechanism to resolve a compensation dispute with a follow-on registrant, and there is no assurance that Monsanto ever will have occasion to resort to arbitration.27 The Act permits the original data submitter and the follow-on applicant to fix the terms and amount of compensation by agreement or to set their own procedures to arrive at such an agreement, and provides for binding arbitration only if the parties after ninety days have been unable to agree on the amount of compensation. FIFRA § 3(c) (1) (D) (ii), 7 U.S.C. § 136a(c) (1) (D) (ii). It is conjectural at this point whether Monsanto will be unable to agree on the terms of compensation with follow-on registrants and whether it therefore will be forced to pursue the arbitration remedy. Monsanto will have ample opportunity to test the constitutional validity of the arbitration scheme should it ever

<sup>&</sup>lt;sup>28</sup> As even Monsanto has noted, nothing in the opinion below addresses the validity of the arbitration scheme apart from its adequacy as a means of providing just compensation. See Motion to Affirm at 24 & n.24.

<sup>&</sup>lt;sup>27</sup> By contrast, the meaning of compensation and the authority of arbitrators under FIFRA is squarely raised in *PPG Industries*, *Inc. v. Stauffer Chemical Co.*, No. 83-1941 (filed July 7, 1983), now pending in the United States District Court for the District of Columbia.

invoke that mechanism. See Babbitt v. United Farm Workers National Union, 442 U.S. 289, 304-05 (1979). Accordingly, if the Court affirms the portion of the district court's judgment relating to the taking claim, it should still reverse its decision on the arbitration scheme and direct it to dismiss that portion of the complaint.<sup>28</sup>

#### CONCLUSION

The district court's judgment should be reversed and the case remanded to that court with directions to dismiss the complaint.

Respectfully submitted,

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November 25, 1983

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<sup>&</sup>lt;sup>28</sup> Another very practical reason to direct the district court to dismiss the complaint is to avoid any further effort by Monsanto to obtain indirectly the same anticompetitive relief it has obtained to date in this case, by arguing that some constitutional taint of the arbitration scheme requires that the entire FIFRA follow-on procedure be invalidated. This is precisely the position that Monsanto has asserted in the pending *Union Carbide* case (see p. 14 supra) and presumably would assert on remand if the opportunity were presented.

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No. 83-196

CLERK

#### IN THE

# Supreme Court of the United States

OCTOBER TERM, 1983

WILLIAM D. RUCKELSHAUS, ADMINISTRATOR, UNITED STATES ENVIRONMENTAL PROTECTION AGENCY,

Appellant,

V.

MONSANTO COMPANY,

Appellee.

On Appeal From The United States District Court For The Eastern District Of Missouri

# BRIEF FOR PPG INDUSTRIES, INC. AS AMICUS CURIAE

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November 23, 1983

### TABLE OF CONTENTS

	Page
TABLE OF AUTHORITIES	. ii
INTEREST AND POSITION OF THE AMICUS	. 1
SUMMARY OF ARGUMENT	. 3
ARGUMENT	. 5
I. FIFRA Requires That Compensation Be Based On A Sharing Of The Direct Cost Of Test Data Neces sary For Registration	
A. The Statute and Its Legislative History	
B. Adminstrative Interpretation of Section 3(c)(1)(D)(ii)	
C. Judicial Decisions	. 14
II. FIFRA Provides For Judicial Review Of Arbitration Awards	
CONCLUSION	. 19

## TABLE OF AUTHORITIES

CASES: Pag	ge
Amchem Products, Inc. v. GAF Corp., 594 F.2d 470 (5th Cir.), modified, 602 F.2d 724 (5th Cir. 1979)	15
Charles Wolff Packing Co. v. Court of Industrial Rela-	18
	15
Chevron Chemical Co. v. Costle, 641 F.2d 104 (3rd Cir.), cert. denied, 452 U.S. 961 (1981)	14
Ciba-Geigy Corp. v. Farmland Industries, Inc., FIFRA COMP. Dkt. Nos. 33, 34, & 41 (Aug. 19, 1980), Final Order issued by the Judicial Officer (Apr. 30, 1981), affirmed by the Administrator (July 28, 1981).	13
IAM v. Street, 367 U.S. 740 (1961)	6
Immigration & Naturalization Service v. Chadha, 103 S. Ct. 2764 (1983)	
International Brotherhood of Electrical Workers v. E.I.  DuPont de Nemours & Co., 420 F. Supp. 208 (E.D. Va. 1976)	
	18
Mobay Chemical Corp. v. Costle, 12 Env't Rep. Cas. (BNA) 1572 (W.D. Mo. 1978), appeal dismissed for want of jurisdiction, 439 U.S. 320 (1979)	
(per curiam) 7, 8,	15
Mobay Chemical Corp. v. Costle, 447 F. Supp. 811 (W.D. Mo. 1978), modified, 517 F. Supp. 252 (W.D. Pa. 1981), aff'd sub nom. Mobay Chemical Corp. v. Gorsuch, 682 F.2d 419 (3d Cir.), cert. denied, 103 S. Ct. 243 (1982)	10
343 (1982)	10
	17
Mount St. Mary's Hospital v. Catherwood, 26 N.Y.2d	18
National Agricultural Chemicals Association v. EPA, 554 F. Supp. 1209 (D.D.C. 1983)	7

## **Table of Authorities Continued**

	Page
Northern Pipeline Construction Co. v. Marathon Pipe Line Co., 458 U.S. 50 (1982)	5, 16
Piggly Wiggly Operators' Warehouse, Inc. v. Piggly Wiggly Operators' Warehouse Independent Truck Drivers Union, 611 F.2d 580 (5th Cir. 1980)	17
Totem Marine Tug & Barge, Inc. v. North American Towing, Inc., 607 F.2d 649 (5th Cir. 1979)	17
Union Carbide Agricultural Products Co. v. Ruckelshaus, No. 76 Civ. 2913 (RO) (S.D.N.Y. July 28, 1983)	5
Union Carbide Agricultural Products Co. v. Thompson- Hayward Chemical Co., FIFRA COMP. Dkt. No. 27 (July 13, 1982)	
United Farm Workers v. Babbitt, 449 F. Supp. 449 (D. Ariz. 1978), rev'd on other grounds, 442 U.S. 289 (1979)	18
United States v. Raddatz, 447 U.S. 667 (1980)	5
United States Postal Service v. National Rural Letter Carriers Association, 535 F. Supp. 1034 (N.D. Ohio 1982)	17
United Steelworkers of America v. Enterprise Wheel & Car Corp., 363 U.S. 593 (1960)	17
Washington Hospital Center v. Service Employees International Union, 112 L.R.R.M. (BNA) 3008 (D.D.C.	17
1983)	17
Zeigler Coal Co. v. District 12, United Mine Workers of America, 484 F. Supp. 445 (C.D. Ill. 1980)	17
STATUTES:	
Federal Insecticide, Fungicide, and Rodenticide Act,	
Section 3(c)(1)(D), 7 U.S.C. § 136a(c)(1)(D)	1, 16
Section 3(c)(1)(D)(ii), 7 U.S.C. § 136a(c)(1)(D)(ii)	
Section 3(c)(5)(D), 7 U.S.C. § 136a(c)(5)(D)	6
Federal Pesticide Control Act of 1978, Pub. L. No. 95-	
396, 92 Stat. 819	10

### **Table of Authorities Continued**

	Page
REGULATIONS:	
40 C.F.R. § 162.9-2 (1983)	14
40 C.F.R. § 162.9-4 (1983)	6, 14
38 Fed. Reg. 31862 (Nov. 19, 1973)	9
LEGISLATIVE HISTORY:	
S. Rep. No. 838 (Part II), 92nd Cong., 2d Sess., reprinted in 1972 U.S. Code Cong. & Ad. News 3993 7,	8, 9
S. Rep. No. 970, 92d Cong., 2d Sess., reprinted in 1972 U.S. Code Cong. & Ad. News 3993	8
S. Rep. No. 452, 94th Cong., 1st Sess., reprinted in 1975 U.S. Code Cong. & Ad. News 1359	9
S. Rep. No. 334, 95th Cong., 1st Sess. (1977)	10
H.R. Rep. No. 497, 94th Cong., 1st Sess. (1975)	10

### IN THE

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OCTOBER TERM, 1983

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WILLIAM D. RUCKELSHAUS, ADMINISTRATOR, UNITED STATES ENVIRONMENTAL PROTECTION AGENCY,

Appellant,

V.

MONSANTO COMPANY,

Appellee.

On Appeal From The United States District Court For The Eastern District Of Missouri

# BRIEF FOR PPG INDUSTRIES, INC. AS AMICUS CURIAE

PPG Industries, Inc., ("PPG") submits this brief amicus curiae having obtained written consent from both parties. This brief supports the constitutionality of the compulsory arbitration provision of the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"). 7 U.S.C. § 136a(c)(1)(D)(ii) (1982).

### INTEREST AND POSITION OF THE AMICUS

PPG manufactures and sells the pesticide butylate, a product originally developed and registered under FIF-RA by Stauffer Chemical Company ("Stauffer"). When it sought its two butylate registrations, PPG cited test data previously submitted to the United States Environmen-

tal Protection Agency ("EPA") by Stauffer, in accordance with FIFRA's "follow-on" registration program. As the statute commands, PPG offered Stauffer compensation for EPA's reliance on Stauffer's test data in granting PPG's registrations. When the parties were unable to agree on the amount of compensation, Stauffer initiated binding arbitration, as mandated by the statute. An arbitration award was rendered, which PPG has challenged in the Federal District Court for the District of Columbia. PPG Industries, Inc. v. Stauffer Chemical Co., No. 83-1941 (filed July 7, 1983). This is the first and only award ever issued under the compulsory arbitration provision of the Act.

PPG's interest in the present case is direct and substantial. As a follow-on registrant of a pesticide originally developed and registered by a competitor, PPG has a vital interest in both of the central questions raised: (1) whether the statutory provisions permitting reliance on the original registrant's test data are constitutional; and (2) whether the compulsory arbitration provision of the Act is constitutional.

The decision below that the mandatory arbitration feature of the statute is unconstitutional is inextricably linked to its holding that the follow-on registration provision of FIFRA constitutes a taking. The taking issue dominates the opinion, and the decision on the arbitration provision is made without any consideration whatsoever of the extensive legislative history and judicial and administrative precedents defining the meaning of compensation under the statute.

We agree with the Government that the question of the constitutionality of the arbitration provision is not ripe for review in this case, and therefore should not be decided by the Court. PPG's district court action will afford

ample opportunity to resolve that issue; indeed, PPG has squarely raised the issue in a motion for summary judgment in that case. Should this Court, however, reach that issue, we present our position here on the constitutionality of the arbitration provision.

This brief will not address the taking question, as we believe that issue will be fully briefed and presented by the Government. We discuss only the constitutionality of the arbitration provision. It is our position that the arbitration provision is constitutional only if there are defined substantive standards limiting the arbitrators' discretion, and if the Act also provides for judicial review of awards to assure compliance with such standards. As we show, when read in light of its legislative history, the Act provides standards for determining compensation, and also provides for judicial review. For these reasons, the arbitration provision satisfies the requirements of the Constitution.

#### SUMMARY OF ARGUMENT

In Northern Pipeline Construction Co. v. Marathon Pipe Line Co., 458 U.S. 50 (1982), this Court recognized a narrow exception to the general principle that the federal judicial function can be performed only by Article III ourts. That exception permits non-Article III decision-makers, such as administrative agencies, masters, and arbitrators, to adjudicate federally created rights, but only if their discretion is limited by clearly defined legislative standards and their decisions are subject to adequate judicial review. To be constitutional, therefore, the compulsory arbitration provision of FIFRA must meet that test. We submit that it does.

The compulsory arbitration provision in Section 3(c)(1)(D)(ii) of FIFRA must be construed in light of its

purposes and legislative history. So construed, it defines a narrow, fact-finding role for arbitrators to resolve compensation disputes. That role is to determine the direct costs incurred by the original registrant in developing the test data relied on by the follow-on registrant, and to apportion those costs fairly, equitably, and reasonably between the parties. Arbitrators who go beyond this limited statutory function run afoul of the substantive standard established by the Act.

The follow-on registration procedures in Section 3(c)(1)(D) of FIFRA were designed by Congress as an effective way to avoid wasteful and duplicative testing by industry and review by EPA, to reduce costs and minimize delays, and to enhance competition in the pesticide industry. The statute was not intended to provide economic windfalls to original registrants, create barriers to market entry, or effectively extend the duration of patent grants beyond the time provided by law. Accordingly, compensation awards under FIFRA must be based only on the costs incurred by the initial pesticide registrant in developing the relevant test data required by EPA, and must be limited to a fair share of those costs. FIFRA does not contemplate or authorize a wide-open, limitless inquiry into other factors, such as the economic "value" or "benefit" to a follow-on registrant in relying on the data filed by the original registrant.

The judicial review provision in Section 3(c)(1)(D)(ii), although limited in scope, allows federal district courts to determine whether an arbitration award is in accordance with law, and whether the arbitrators have exceeded their authority by basing the award on factors not permitted by the Act. Accordingly, the judicial review provision satisfies the constitutional requirement laid down in Northern Pipeline, supra.

#### ARGUMENT

The court below relied on Northern Pipeline, supra, as support for its holding that FIFRA's mandatory arbitration provision is unconstitutional. J.S. App. at 34a-35a. Accord Union Carbide Agricultural Products Co. v. Ruckelshaus, No. 76 Civ. 2913 (RO) (S.D.N.Y. July 28, 1983), slip. op. at 9. If FIFRA were to be construed—erroneously, in our view—to allow an open-ended, standardless arbitration proceeding, with no opportunity for judicial review, these decisions would be correct. But this is not the case.

To survive constitutional scrutiny the arbitration provision must meet two fundamental criteria articulated in Northern Pipeline: (a) it must provide substantive standards limiting the role of arbitrators, and (b) it must afford an opportunity for judicial review of the arbitrator's award. As this Court stated:

[I]t is clear that when Congress creates a substantive federal right, it possesses substantial discretion to prescribe the manner in which the right may be adjudicated—including the assignment to an adjunct of some functions historically performed by judges . . . . [However,] the functions of the adjunct must be limited in such a way that "the essential attributes" of judicial power are retained in the Art. III court.

Northern Pipeline, 458 U.S. at 80-81 (quoting Crowell v. Benson, 285 U.S. 22, 51 (1932)). For the FIFRA arbitration provision to satisfy the "adjunct exception," the arbitrators must perform "statutorily channeled fact-finding functions," Northern Pipeline, 485 U.S. at 85, and "the ultimate decision [must be] made by the district court," United States v. Raddatz, 447 U.S. 667, 683 (1980).

It is axiomatic that federal statutes have a presumption of constitutionality, *Immigration & Naturalization Serv-*

ice v. Chadha, 103 S. Ct. 2764, 2780 (1983), and should be construed so as to uphold their constitutionality, IAM v. Street, 367 U.S. 740, 749 (1961). FIFRA is susceptible to such a construction.

A careful reading of Section 3(c)(1)(D) of FIFRA and its legislative history shows that the arbitrators' authority in data compensation proceedings is narrowly defined. Moreover, FIFRA provides adequate review authority for federal district courts to ensure that arbitrators do not exceed their statutory authority by basing their awards on criteria not permitted by the Act.

- FIFRA Requires That Compensation Be Based On A Sharing Of The Direct Cost Of Test Data Necessary For Registration.
  - A. The Statute and Its Legislative History.

FIFRA is a health and safety statute requiring prospective pesticide sellers to register products with EPA. That Agency may not grant a registration until it analyzes the submitted data and finds that the pesticide will not cause "unreasonable adverse effects on the environment." 7 U.S.C. § 136a(c)(5)(D). Section 3(c)(1)(D) requires applicants for registration to submit to EPA test data concerning the safety of their products.

The statute recognizes in Section 3(c)(1)(D)(ii) that other applicants may seek to register a product identical or substantially similar to one previously registered, and permits such follow-on applicants to rely on data already in the Agency's files, provided they offer to compensate the original data submitter. This procedure was de-

<sup>&</sup>lt;sup>1</sup> From 1978 through 1983 EPA's "cite-all" regulation required all follow-on registrants to rely on previously submitted data. 40 C.F.R. § 162.9-4 (1983). The cite-all regulation eliminated any incentive for a

signed to prevent "the necessity of costly duplicative testing in order to produce governmentally-mandated data without thereby casting the entire [financial] burden upon the party first to meet the government's requirements by producing and submitting that data." Mobay Chemical Corp. v. Costle, 12 Env't Rep. Cas. (BNA) 1572, 1578 (W.D. Mo. 1978), appeal dismissed for want of jurisdiction, 439 U.S. 320 (1979) (per curiam) (emphasis added). If follow-on registrants could not rely on previously submitted data, the resultant duplicative testing "would represent a wasteful, time-consuming, and costly process resulting in a substantial misallocation of resources." S. Rep. No. 838 (Part II), 92d Cong., 2d Sess. 72, reprinted in 1972 U.S. Code Cong. & Ad. News 3993, 4092.

The legislative history of Section 3(c)(1)(D) exhibits a basic, recurring theme: compensation is limited to a fair and equitable sharing (or partial reimbursement) of the direct costs incurred by the original registrant in producing test data necessary for registration.

Prior to 1972, EPA routinely considered relevant data contained in its files to evaluate new applications for a previously registered pesticide. See, e.g., S. Rep. No. 838

follow-on registrant to perform and submit its own tests, since it would be required in any case to compensate previous submitters of data. The regulation was in effect at all times pertinent to PPG's registrations of butylate.

Two years after PPG had obtained its follow-on registrations and while the PPG-Stauffer arbitration was pending, a district court held that the cite-all regulation "exceed[ed] the regulatory authority granted to the EPA by Section 3(c) of FIFRA." National Agricultural Chem. Ass'n v. EPA, 554 F. Supp. 1209, 1212 (D.D.C. 1983). The Court permanently enjoined EPA from denying follow-on registration applications based solely upon the applicant's own data. Id.

(Part II) 92d Cong., 2d Sess. 18-19, reprinted in 1972 U.S. Code Cong. & Ad. News 3993, 4040-41; Mobay Chemical Corp. v. Costle, 12 Env't Rep. Cas. (BNA) 1572, 1580 n.22 (W.D. Mo. 1978), appeal dismissed for want of jurisdiction, 439 U.S. 320 (1979) (per curiam).

In 1972, Congress considered substantive amendments to FIFRA and for the first time enacted a follow-on registration provision that required a subsequent registrant to pay compensation to the initial registrant. Large pesticide producers wanted to preclude reliance by subsequent registrants on data previously submitted by others to EPA and lobbied for "exclusive use" amendments to FIFRA. In considering and rejecting exclusive use proposals, the Senate Committee on Commerce found that such provisions would erect

barriers to entry in the pesticides industry... which go far beyond that envisioned by our patent system. In effect, whether or not a pesticide has patent protection, a manufacturer wishing to register a pesticide previously registered would have to duplicate the required test data.... In the extreme, a monopoly in the production of a pesticide could ensue if competitors are unable to afford the sometimes costly safety and efficacy tests.

S. Rep. No. 970, 92d Cong., 2d Sess. 12, reprinted in 1972 U.S. Code & Ad. News 3993, 4096.

The legislation enacted in 1972 established a system allowing EPA to rely on test data already in EPA's files, provided the follow-on registrant offered to pay compensation to the initial registrant and submit data compensation disputes to EPA administrative law judges. Compensation was to be limited to a "system under which permission to use the test data in return for a reasonable share of the cost of producing the data would be required." S. Rep. No. 838, (Part II), 92d Cong., 2d Sess.

69, reprinted in 1972 U.S. Code Cong. & Ad. News 3993, 4089 (emphasis added). A statement of legislative intent accompanying the proposed legislation explained that "fairness and equity require a sharing of the governmentally required cost of producing the test data used in support of the [subsequent application]." Id. at 72-73, reprinted in 1972 U.S. Code Cong. & Ad. News at 4092 (emphasis added). Requiring subsequent applicants to produce their own test data "would represent a wasteful, time-consuming, and costly process resulting in a substantial misallocation of resources." Id., reprinted in 1972 U.S. Code Cong. & Ad. News at 4092.

In 1975, Congress again amended FIFRA to eliminate uncertainty as to whether data submitted to EPA prior to 1972 were compensable. Congress resolved the question by establishing a cut-off date of January 1, 1970, thereby codifying a regulatory policy adopted by EPA as early as 1973. See 38 Fed. Reg. 31862 (Nov. 19, 1973). In its consideration of the 1970 cut-off, the Senate Committee on Agriculture and Forestry reported that "to require cost sharing with respect to 'old data' [pre-1970] . . . could create a windfall for producers of this data since such data was prepared without any reasonable expectation that the law would require sharing of the costs of production." S. Rep. No. 452, 94th Cong., 1st Sess. 10, reprinted in 1975 U.S. Code Cong. & Ad. News 1359, 1367-68 (emphasis added). The Committee confirmed that Section 3(c)(1)(D) was designed "to provide for equitable sharing among industry members of the cost of producing data necessary to obtain or continue a registration under the Act." Id., reprinted in 1975 U.S. Code Cong. & Ad. News at 1367 (emphasis added).

Moreover, several members of the House Committee on Agriculture, which also considered the 1975 amendments, stated in supplemental views contained in the Committee Report:

Reasonable compensation should be an equitable sharing of the direct costs of producing governmentally required test data. It should not be based upon a "value" basis. No profit should accrue to the original applicant . . . .

H.R. Rep. No. 497, 94th Cong., 1st Sess. 65 (1975) (emphasis in original).

FIFRA was again amended in 1978. The substantive standard for compensation, cost-sharing, was not altered. Congress did, however, change the process for resolving compensation disputes by providing for mandatory arbitrations to be conducted under the auspices of the Federal Mediation and Conciliation Service.<sup>2</sup>

The legislative history of the 1978 amendments expresses reaffirmation of the cost-sharing standard for compensation. The Senate Report recognized "the cost of data development and the need for cost-sharing among registrants." S. Rep. No. 334, 95th Cong., 1st Sess. 4 (1977) (emphasis added). The Report went on to explain:

The amendments in S. 1678 recognize the proprietary interest in health and safety data on the part of

<sup>&</sup>lt;sup>2</sup> Congress also amended Section 3(c)(1)(D) to provide a limited form of exclusive use protection for future data submitted for innovative products and uses. Specifically, Congress provided that data submitted after September 30, 1978, for new products and new uses for those products could receive up to 10 years of exclusive use protection (i.e., no follow-on registrations could be based on that data) followed by a limited period of five years during which compensation could be obtained. Pub. L. No. 95-396, § 2, 92 Stat. 819 (1978) (codified at 7 U.S.C. § 136a(c)(1)(D) (1982)). This incentive for new products was provided without at the same time creating windfalls to those who had registered products before 1978.

pesticide registrants who underwrite the expense of obtaining such data. It eliminates the "free-rider" situation to which industry has objected, but keys the amount of payment by subsequent registrants to the costs of developing data necessary for government approval, not the costs of developing the pesticide. The amendments also avoid an extension of the patent rights on chemicals.

### Id. at 31 (emphasis added).

The cost-sharing standard of compensation is unequivocally established in the legislative history, and is the only interpretation consistent with the structure of the statute. FIFRA allows the applicant the option to submit "a full description of the tests made and the results thereof upon which their claims are based, or alternatively a citation to data that appear in the public literature or that previously had been submitted to the Administrator .... 7 U.S.C. § 136a(c)(1)(D). Given the choice provided by Congress for a follow-on registrant to submit its own data or offer compensation, and given the congressional intention to avoid costly and wasteful duplicative testing, compensation must amount to, and be based on, some share of the cost of producing the data. If compensation could exceed the cost of the data, no follow-on registrant would elect the compensation route, and Congress' intentions to avoid duplicative testing and enhance competition would be frustrated.

The legislative history is consistent throughout. Whenever Congress discussed the meaning of compensation, it defined compensation as based on an equitable and reasonable share of the direct costs of providing the test data necessary for registration.

#### B. Administrative Interpretation of Section 3(c)(1)(D)(ii).

Prior to the procedural amendments to FIFRA establishing mandatory arbitration for data compensation disputes, an EPA administrative law judge ("ALJ") was assigned that responsibility. Two compensation cases were decided, both by ALJ Gerald Harwood, Ciba-Geigy Corp. v. Farmland Industries, Inc., FIFRA COMP. Dkt. Nos. 33, 34 & 41 (Aug. 19, 1980), Final Order issued by the Judicial Officer (Apr. 30, 1981), affirmed by the Administrator (July 28, 1981), and Union Carbide Agricultural Products Co. v. Thompson-Hayward Chemical Co., FIFRA COMP. Dkt. No. 27 (July 13, 1982). Judge Harwood undertook in both cases an exhaustive analysis of the statute and its legislative history. In each opinion, he rejected an award in excess of data costs, as proposed by the original data submitter. Instead, the decisions concluded that Congress intended follow-on registrants to pay a fair share of the cost of producing relevant test data previously submitted by the initial registrant.

The ALJ found in each case that cost-sharing implemented the congressional intent of FIFRA: it recognized the private interest of the original data submitter in recovering a portion of its costs and "the equally important public interest of keeping costs of entry into the pesticide business attributable to government regulation as low as possible." Farmland, slip op. at 46. Moreover, the compensation requirement itself was not to be used as a barrier to entry or to "extend the awards for . . . research and development . . . beyond the period allowed by the patent grant." Id. at 30.3

<sup>3</sup> The ALJ also found

no evidence in the legislative history that Congress believed that patent rights, or in their absence, exclusive use of data, would be inadequate to maintain research and development in pesticides.

Farmland, slip op. at 34 n.45.

The second FIFRA compensation decision, *Union Carbide*, succinctly summarized the underlying purpose and scope of compensation:

FIFRA, of course, added another dimension to the marketing of pesticides, namely the additional cost in getting a product to market that may be imposed by FIFRA's registration requirements. It seems clear from the legislative history that Congress felt as a matter of fairness, if for no other reason, that the first registrant should not be saddled with the entire burden of this additional cost. But it would appear that it was only with the incremental cost of obtaining a registration that Congress appears to have been concerned about, and the desirability of neutralizing any adverse effect on research and development which would be caused if the entire testing cost were imposed on the first registrant. Over and above this, the incentive for research and development, and a company's investment in it, would still have to come from the profits to be gained in the sale of the product and from whatever competitive advantage accrued to it from patents or secret processes.

### Id. at 21.

In Farmland and Union Carbide, the initial registrants requested an amount far exceeding their own investment in the test data required for registration. In each, the amount requested by the initial registrant far exceeded what the follow-on registrant would have had to pay to prepare its own test data packages for EPA. The ALJ rejected these requests and issued an award based on cost-sharing. In Farmland the award was \$240,682, and in Union Carbide \$51,760.

The ALJ's interpretation of Section 3(c)(1)(D) is consistent with EPA's regulations implementing that provision. EPA's regulations included an offer-to-pay state-

ment, which EPA required all registration applicants to sign, establishing the legal scope of the offer to compensate. See 40 C.F.R. §§ 162.9-2, 162.9-4 (1983). This statement limited the compensation obligation to data submitted by the original registrant that were scientifically relevant to the follow-on applicant's registration. It required each applicant to acknowledge that it "relies on ... [e]ach ... item of data in the Agency's files" that "concerns the properties or effects of" applicant's product or one identical or substantially similar to it and "[i]s one of the types of data that EPA would require to be submitted for scientific review by EPA if the application sought the initial registration [of the product] under FIF-RA... under the data requirements in effect on the date EPA approves applicants' present application." 40 C.F.R. § 162.9-4 (1983).

### C. Judicial Decisions.

The major judicial precedents relied upon by the Government to support the position that Section 3(c)(1)(D) of FIFRA does not constitute a taking of an original data submitter's property also demonstrate that compensation is limited to a sharing of registration test data costs. For example, in *Chevron Chemical Co.* v. Costle, 641 F.2d 104 (3d Cir.), cert. denied, 452 U.S. 961 (1981), the court quoted FIFRA's legislative history in explaining its understanding of compensation under Section 3(c)(1)(D):

[I]t was decided that fairness and equity required a sharing of the governmentally required cost of producing the test data used in support of an application by an applicant other than the originator of such data.

641 F.2d at 109 (footnote omitted) (emphasis added). See also Amchem Products, Inc. v. GAF Corp., 594 F.2d 470,

481 (5th Cir.), modified, 602 F.2d 724 (5th Cir. 1979); Chevron Chemical Co. v. Costle, 443 F. Supp. 1024, 1028 n.2 (N.D. Cal. 1978) (purpose of data compensation was "saving the cost of duplicative test data").

In Mobay Chemical Corp. v. Costle, 12 Env't Rep. Cas. (BNA) 1572 (W.D. Mo. 1978), appeal dismissed for want of jurisdiction, 439 U.S. 320 (1979) (per curiam), a three-judge court concluded that the compensation system under FIFRA provided limited protection to "the expenditure of the first applicant in generating the data." Id. at 1578. The court added that

neither the legislative history nor the plain language of § 3 indicate[s] that in adopting its regulatory scheme Congress was concerned with ensuring maintenance of competitive commercial positions of the original submitters of data. Rather, the Congressional concern in adopting the original § 3(c)(1)(D) in 1972 was for maximum allocation of resources in the public interest—preventing the necessity of costly duplicative testing in order to produce governmentally-mandated data without thereby casting the entire burden upon the party first to meet the government requirements by producing or submitting that data.

Id. (citing S. Rep. No. 838 (Part II), 92d Cong., 2d Sess.72-73 (1972)) (emphasis added).

Finally, in another case, also entitled Mobay Chemical Corp. v. Costle, 447 F. Supp. 811 (W.D. Mo. 1978), modified, 517 F. Supp. 252 (W.D. Pa. 1981), affd sub nom. Mobay Chemical Corp. v. Gorsuch, 682 F.2d 419 (3d Cir.), cert. denied, 103 S. Ct. 343 (1982), the court rejected a broad-based attack on the FIFRA registration system, and concluded:

But FIFRA was not intended to shelter pesticide registrants from the rigors of commercial competi-

tion. The protection afforded by § 3(c)(1)(D) extends only to compensation for producing the test data used in the registration process, and not to the ultimate economic or commercial benefits which may flow from the registration itself.

447 F. Supp. at 834 (emphasis added).

Just as these courts were correct in determining that the follow-on registration provision does not constitute a taking of property under the Fifth Amendment, their analyses of the scope of compensation were also correct; as shown above, cost-sharing is soundly based in the legislative history of Section 3(c)(1)(D).

# FIFRA Provides For Judicial Review Of Arbitration Awards.

In its case pending in district court, PPG has contended that there is adequate authority in the statute to allow federal district courts to determine whether arbitrators have exceeded their authority under FIFRA. In the absence of such provision for judicial review, the mandatory arbitration provision would fail the test of Northern Pipeline.

Section 3(c)(1)(D)(ii) allows arbitration awards to be reviewed for "fraud, misrepresentation, or other misconduct by one of the parties to the arbitration or the arbitrators." 7 U.S.C. § 136a(c)(1)(D)(ii). In the PPG-Stauffer arbitration, the arbitrators correctly recognized that "'misconduct' on the part of arbitrators can include their acting in excess of their powers, or 'perversely misconstruing the law.' "Award at 2 n.\* (quoting Amicizia Societa Navigazione v. Chilean Nitrate Etc., 184 F. Supp. 116 (S.D.N.Y. 1959), affd, 274 F.2d 805 (2d Cir. 1960)). This statutory provision satisfies the need for judicial review. There is no justification for attributing to

Congress any intent to abrogate the settled principles of judicial review of arbitration awards.

As this Court has recognized, arbitration decisions are subject to judicial review to ensure that the arbitrators have not exceeded their lawful authority. United Steelworkers of America v. Enterprise Wheel & Car Corp... 363 U.S. 593 (1960). Arbitrators' powers are circumscribed by the source from which their authority is derived. Monongahela Power Co. v. Local No. 2332, 566 F.2d 1196, 1199 (4th Cir. 1976). Whether arbitrators have exceeded the scope of their authority "is an issue for judicial resolution." Piggly Wiggly Operators' Warehouse, Inc., v. Piggly Wiggly Operators' Warehouse Independent Truck Drivers Union, 611 F.2d 580, 583 (5th Cir. 1980). When the court finds that arbitrators have exceeded their authority, their awards "cannot be enforced." United States Postal Service v. National Rural Letter Carriers Association, 535 F. Supp. 1034, 1037 (N.D. Ohio 1982).

When arbitrators' authority derives from a contract between the parties, the resultant award is invalid and unenforceable if the arbitrators exceed their powers under the contract. The arbitral award must be overturned unless it "draws its essence from the collective bargaining agreement." Enterprise Wheel & Car Corp., 363 U.S. at 597. Courts will deny enforcement to and vacate arbitral awards that exceed the arbitrators' contractual authority. Totem Marine Tug & Barge, Inc. v. North American Towing, Inc., 607 F.2d 649, 561 (5th Cir. 1979); Washington Hospital Center v. Service Employees International Union, 112 L.R.R.M. (BNA) 3008 (D.D.C. 1983); Zeigler Coal Co. v. District 12, United Mine Workers of America, 484 F. Supp. 445, 447 (C.D. Ill. 1980); International Brotherhood of Electrical Workers v. E.I.

DuPont de Nemours & Co., 420 F. Supp. 208, 210 (E.D. Va. 1976).

Under FIFRA, the arbitrators' power derives not from contract, but from a statute that creates a form of mandatory arbitration. Because of the due process implications of such a procedure, it follows a fortiori that Congress intended federal courts to review FIFRA compensation determinations carefully and vacate the awards if the arbitrators exceed the authority granted them by the statute. So construed, FIFRA is unquestionably constitutional.

The mandatory nature of the arbitration provision raises substantial due process problems. See Charles Wolff Packing Co. v. Court of Indus. Relations, 262 U.S. 522 (1923); Midkiff v. Tom, 471 F. Supp. 871, 883-84 (D. Hawaii 1979); United Farm Workers v. Babbitt, 449 F. Supp. 449, 466 (D. Ariz. 1978), rev'd on other grounds, 442 U.S. 289 (1979). Due process requires that the FIFRA arbitrators be limited to a carefully circumscribed fact-finding role, and not engage in the interpretation of a complex federal statute. See Mount St. Mary's Hospital v. Catherwood, 26 N.Y.2d 493, 311 N.Y.S.2d 863, 872 (Ct. App. 1970) (provision of mandatory "ad hoc tribunals to resolve disputes without limitation to rules of law" is unconstitutional). Due process also requires that there be judicial review adequate to ensure that FIFRA arbitrators' factual findings are supported by evidence in the record and are not arbitrary or capricious. Such safeguards guarantee that the awards "imposed by the arbitrator under the power conferred by statute have a basis not only in his good faith, but in law and the record before him." Id. at 873 (citation omitted).

#### CONCLUSION

For all the reasons set forth above, PPG submits that FIFRA delegates to arbitrators a narrow fact-finding role, subject to judicial review. Thus, the mandatory arbitration provision is constitutional.

Respectfully submitted,

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November 23, 1983

Office · Supreme Court, U.S. FILED JAN 20 1984

In the Supreme Court of the United StatesTEVAS.

October Term, 1983

William D. Ruckelshaus, Administrator, United States Environmental Protection Agency, Appellant

v.

Monsanto Company

ON APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF MISSOURI

BRIEF AMICUS CURIAE OF SATHON, INC.

Ralph E. Brown
Prudential Plaza, Suite 2500
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# TABLE OF CONTENTS

Tabl	e of	Authorities	•	•	iii
I.		erest of Amicus Curiae			. 1
II.	Argu	ument			
	1.	Constitutionality of Com- pulsory Arbitration is Ripe for Review			. 2
4	2.	The Compulsory Arbitration is Unconstitutional Because it Violates Due Process Guarantees of the Fifth and Fourteenth Amendments			. 9
	3.	The Compulsory Arbitration is Unconstitutional Because it Vests Judicial Power in Tribunals Not Created Under Article III of the Constitution			.10
	4.	The FIFRA Arbitration Provisions Are Unconstitutionally Vague			.19
	5.	The Compulsory Arbitration Is Unconstitutional Because of Absence of the Right to a Jury Trial			.29
	6.	The Compulsory Arbitration is Unconstitutional Because of the Absence of Safeguards for Procedural Due Process .			.30

	7.	Conc	Federa iliatio out Au	on S	erv	ice	W	as						
		gate	FIFRA	Arb	itra	ati	on	s	to					
			America ciation			· ·	·	on.		•			•	35
	8.		Challe											
			he Sta											
			the Pi											
	1	Use	and Da	ta C	ompe	ens	at	10	n	•	•	•	•	38
		(1)	Genera	al P	rino	cip	le	s	of					
			sever	abil	ity	•	•	•	•	•	•	•	•	38
		(2)	The Cl											
			sions	of	the	St	at	ut	e					
			are Se											
			Rest	of th	ne S	Sta	tu	te	•	•	•	•	•	40
		(3)	The Ch											
			pulson	ry A	rbit	ra	ti	on						
			Provis	sion	s ar	ce	No	t						
			Severa					-						
			Challe											
			tions	on .	Judi	ici	al							
			Review			•	•	•	•	•	•	•	•	42
		(4)	The Pa											
			of the	19	78 A	Ame	nd	me	nt	S				
			Revive		-									
			Provis											
			Resolu	itio	u pi	t	he	E	PA		•	•	•	45
III.	Cond	clusio	on											47

# TABLE OF AUTHORITIES

CASES:
Abbott Laboratories v. Gardner, 387
U.S. 136 (1967) 7
Amchem Products, Inc. v. GAF Corp.,
594 F.2d 470, (5th Cir. 1979),
modified, 602 F.2d 724 (5th Cir.
1979)
Archawski v. Hanioti, 350 U.S. 532
(1956)
Babbitt v. United Farm Worker Nat'l
<u>Union</u> , 442 U.S. 289 (1979)8,9
Block v. Hirsh, 256 U.S. 135 (1821) 10
Buckley v. Valeo, 424 U.S. 1 (1976) 39,42
Chas. Wolff Packing Co. v. Court
of Industrial Relations, 262
U.S. 522 (1923)9
Champlin Refining Co. v. Corporation
Commission, 286 U.S. 210 (1932)39,42
Chevron Chemical Co. v. Costle, 641
F.2d 104 (3rd Cir. 1981), cert.
denied,452 U.S. 961 (1981) 20,25,40
Chevron Chemical Co. v. Costle, 443
F.Supp. 1024 (N.D. Cal. 1978) 25
Crowell v. Benson, 285 II.S. 22 (1932) 12

Cudah	y Pa U.S.	ick:	1 no	1	19	42	V.		Ho	)1	1	ar	<u>id</u>	,	3	1	5							,	38
			•	,		-	,	•			•	•		•	•		•	•		•	•	•		•	-
Dairy	Que	en	, 1	Inc		V	•	W	00	od		3	16	9	U		s.								
	469	(1	962	2).	•	•	•	•	•	•	•	•	•	•	•		•	•		•	•	•		•	30
Dorch	y v.	K	ans	sas	3,	2	64	1	U.	S		2	8	6	(	1	92	26	)			1	0	,	42
Ex Pa	rte	Bal	ke]	lit	e	C	or	q:			2	79	)	U.	s		4	13	8						
	(192	(9)	•			•	•	•	-		•				•		•	•		•	•	•			11
Goldb	erg	v.	Ke	21	Ly	,	39	7	Ţ	J.	s	•	2	54	1	(	19	7	0	)					7
Hanna	h v.	L	arc	che	2,	3	63	3	U.	S		4	12	0,	,	(	19	96	0	)		•	,		3 1
INS v	. Ch	adl	na.				t	J .	s.						77										
	L.Ed	1.20	1	317	7	(J	ur	ne	-	23	,	1	9	83	3)		•	•	,	•	•	3	9	, 4	42
Mathe	ws v	. 1	216	ir	id	ge		4	24	1	U	. 5		-	3 1	9									
	(197																•	•	1	•	•	•	,		31
Mobay																									
	Env'																								
	1978																		t						
	of j																						_		
	(197	9)	(1	pe		cu	ri	a	m )	)	•	•	•	•	•		•	•		•	٠	2	5	, 4	26
Mobay	Che	mi	cal	1 (	Co	rp		v		C	0	st	:1	e	,	4	47	7							
	F. S	upi	٥.	8	11	,	(1	١.	D,		Mo	0.		19	7	8	)								
	modi	fi	ed.	. !	51	7	F.		Sı	מנ	D		2	52	2										
	(W.E	). 1	Pa		19	81	1.		af	Ef	i,	d	s	ut	0	n	on	n.							
1	Moba	v (	Che	em:	ic	al	6	0	rı	0.	1	Ţ.		Go	or	S	uc	h							
	682	F.	20	1 4	11	9	13	ir	d	C	i	<u>.</u>		19	9.8	2	1	-	•						
	cert	. ,	la f	116	he		10	13	-		-	C+			R A	3	,								
•	(198	2)						•			•	•	•	•			•	•		•	•	2	6	, :	27
North	ern	Pi	pe l	lir	ne	C	or	15	tr	cu	C	t i	0	n	C	0		v							
	Mara																								
	50 (								_	_	-									. 1	10-	- 1	9		32

Thom																													
	(	19	14	) .		•	•		•	•		•	•		•	1	•	•		•	•	٠	•		•	•		•	30
Unit	ed	S	ta	te	25	,	, .		R	ad	ld	at	tz	,		4	47	,	U	. 5	3.	66	57						
	(	19	80	) .		•	•		•	•		•	•		•		•	•		•	•	•	•		•	•		•	13
Wils	on	v		No	W		2	4	3	U		S		2	8	6	(	1	9	80	))	•			•			•	10
Worl	d-1	Wi	de	V	70	11	S	w	ag	ge	n	(	Co	r	p		v												
	We	00	ds	or	1,	4	14	4	ı	J.	S	•	2	8	6		( 1	9	8	0		•	•		•	•		•	35
UNIT	ED	s	TA	TE	S	(	0:0	N	S	rI	Т	UI	ΓI	0	N														
Art.	I	II															. 1		5	. 1	10-	-19		3	2,	3	3		46
Amen	d.	V																							· P	a	S	5	im
Amen	đ.	V	II													•									1,	2	9.	-	30
Amen Amen Amen	đ.	X	IV	•		•	٠		•	•		•	•		•	•	•	•		•	•	•	•		•	9	,		34
STAT	UTI	ES																											
Fede	R	bc	en		i	de	•	A														c.							
	Se	90	ti	on	1	3,	C	7	,	J.	S	.(	· ·		1:7	36	Sa J.	S	_	ċ.	•	•	•		•	•		•	1
				13	6	a (	C	)	(	1)	(	D	) .									•						. '	40
	Se	ec	t 1	13	6	3 ( a (	C	)	(	1)	(	D)	) ( ) (	1	i	) , ) .		7		υ.	s.	с.			. 0	a	S	s	im
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				13	6	a (	C	)	(2	2)	(	A)			•			•		•	•	:							3
	Se	ec.	ti	on	1	10	,		7	U		s.	.C	•		13	36	h		•			•			•	,		10
	Se	ec	ti	on	1	24	1 (	1	) ,	•	7	Ţ	J.	S	.(	С.	•	1	3	6)		•	•		•	•	,	. :	39
Tuck	er	A	ct	,	2	8	U	. :	S	.c	•	1	14	9	1					•								5	, 8
Pub.	L		No		9	2-	.5	1	6	,	8	6	S	t	at	t.		9	7	3									40
Pub.	L	. 1	No		9	4-	-1	4	0	,	8	9	S	t	al	t.		7	5	1				,			9	. 4	40
Pub.	L	. 1	No		9	5-	.3	9	6	,	9	2	S	t	at	t.		8	1	9							,		43

29	U.S	5.C	•	17	2(	a)														•	. 3	6
29	U.5	S.C.		17	2(	b)															. 3	6
29	U.5	S.C.		17	21	c)															3	6
			•		- '	-,			•	•	•	•	•	•	•	•	•	•	•		-	•
RE	GUL	ATIC	NC	S																		
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29	C.I	R	•	14	04	. 4	,	•		•	•	•	•	•	•	•	•	•	•	•	3	0
29	C.1	. R.	•	14	04	• 1	0	17		•	•	•	•	•	•	•		•	•	•	3	6
29	C.I	·R.	•	14	40	•	•	•	•		•		•	•				•	•		3	7
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H.	R. F	Rep.	. !	95.	-61	63	, 9	)5t	:h	Co	ng	. ,	1	Ist								
	5	ess	3.	(	19	77	) .														4	3
S.	Cor	nf.	R	ge.	. !	95.	-11	88		95	tl	1 0	or	nd.								
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S.	Rep	. (	12.	-8	38		926	1 0	or	a.		20	1 9			•	•	•	•	•	•	•
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	(	197	77	) .														20,	2	١,	2	3

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Ciba-Geigy Corp. v. Farmland Indus-	
tries, .Inc., FIFRA COMP. Dkt.	
Nos. 33, 34, & 41 (Aug. 19,	
1980), Final Order Issued by the	
Judicial Officer (Apr. 30,	
1981), affirmed by the Admini-	
strator (July 28, 1981)	) 4
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Union Carbide Agricultural Products	
Co. v. Thompson-Haywood Chemical	
Co., FIFRA COMP. Dkt. No. 27	
(July 13, 1982)	) Δ
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MIDCELLANGOOD	
16 Am. Jur. 2d, Constitutional Law,	
Section 263	15
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#### INTEREST OF

# AMICUS CURIAE\*

### SATHON, INC.

Sathon sells a pesticide which is registered with the United States Environmental Protection Agency ("EPA") under Section 3 of the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA"), 7 U.S.C. Section 136a. Sathon is a subsequent data user pursuant to FIFRA Section 3(c)(1)(D)(ii), 7 U.S.C. Section 136a (c)(1)(D)(ii) ("Section 3(c)(1)(D)(ii)"). Sathon is being compelled, against its will and contrary to the constitutional guarantees of Article III and the Fifth and Seventh

<sup>\*</sup>Amicus curiae Sathon, Inc. ("Sathon") has secured the consent of both parties herein to the filing of this brief. Counsel for Sathon have transmitted to the Clerk letters of consent from both parties herein.

Amendments, to participate in an arbitration under Section 3(c)(1)(D)(ii).

Sathon contends, as does Monsanto, that the district court correctly held unconstitutional the compulsory arbitration procedures of Section 3(c)(1)(D)(ii) for determining the compensation to be paid by a subsequent data user to an original data submitter.

II.

#### ARGUMENT

# CONSTITUTIONALITY OF COMPULSORY ARBITRATION IS RIPE FOR REVIEW

The question of the constitutionality of compulsory arbitration of pesticide data compensation disputes now before the court is of great importance to the pesticide industry, the EPA and the public. It is ripe for review, no matter how the court rules on the other issues in this case.

The data disclosure issue (whether the data disclosure provisions of FIFRA Sections 3(c)(2) (A) and 10, 7 U.S.C. Sections 136a(c) (2)(A) and 136h, violate the Fifth Amendment) is clearly irrelevant to the constitutionality of compulsory arbitration. Likewise, no matter how the court rules on the data use issue (whether the data use provisions of Section 3(c)(1)(D)(ii) violate the Fifth Amendment), constitutionality of compulsory arbitration is still ripe.

The EPA's contention that the constitutionality of compulsory arbitration is not ripe for review (EPA Br. 45-46) is based on incorrect premises. There have clearly already been applications by subsequent data users, and the trial court expressly found that Monsanto had already received offers to pay from subsequent data users (J.S. App. 21a). Just as clearly, the ninety day period before an arbitration can commence has long

since expired. Compulsory arbitration is fully ripe. An actual arbitration award is not a prerequisite to ripeness of the compulsory arbitation issue. Assuming the data use provisions do not violate the Fifth Amendment and the data compensation provisions are valid\*, then the statutorily established

<sup>\*</sup>It is assumed, arguendo, that the data use provisions of Section 3(c)(1)(D)(ii) (which allow the Administrator to consider data already in the EPA's files, which was submitted by an original data submitter, in support of the application of a subsequent data user) do not violate the Fifth Amendment whether the statute provides for no compensation whatsoever (as was the case with the pre-October 21, 1972 Aceto Chemical Company registrations, J.S. App. 27a) or the statute requires offers to pay like the ones received by Monsanto (J.S. App. 21a). It is further assumed, arquendo, that it is valid to condition the Administrator's consideration of certain data in the EPA's files on the subsequent data users' making an offer to compensate the original data submitter.

method\*\* for Monsanto to obtain any compensation would be to initiate binding arbitration, a procedure which Monsanto strenuously urges is unconstitutional. Indeed, at any moment, Monsanto can be involuntarily and unconstitutionally compelled to arbitrate by any of the applicants who have already made an offer to Such an arbitration deprives the arbitrants of important procedural safeguards, including their rights to the benefits of an Article III court, definite standards for compensation, the right to a jury trial and other forms of due process. Contrary to the EPA's assumption (EPA Br. 45-46), the amount

<sup>\*\*</sup> Monsanto may have other ways to obtain compensation, including but not limited to actions based on unjust enrichment and quasi-contract which it can assert in any court of competent jurisdiction. Moreover, Monsanto may have a Tucker Act remedy for any taking from the use of its data.

of compensation is not the only thing that matters to parties to a pesticide data compensation dispute. They also have a vital interest in having compensation determined by a procedure which in addition to being fundamentally fair, efficient and economical, comports with the Constitution. Assuming the data use and data compensation provisions are valid, there need not be a specific arbitration award before the issue of constitutionality of compulsory arbitration is ripe. An award will not make the issue any more ripe since the statute effectively precludes judicial review, and by the time the award is made the harm will already have been inflicted both on Monsanto and on any other party to the dispute. Even if the data compensation provisions are deemed a windfall for the data submitter, a sort of welfare program bestowed by Congress on large wealthy chemical companies, such a program is still subject to v. Kelly, 397 U.S. 254 (1970). This case satisfies the twofold test for ripeness of Abbott Laboratories v. Gardner, 387 U.S. 136, 149 (1967), which is that the issue be purely a legal one of the sort that is traditionally appropriate for judicial decision, and failure to decide this issue would impose severe hardship on the parties.

on the other hand, if the data use provisions violate the Fifth Amendment, the issue of compulsory arbitration is still ripe. The district court held that Section 3(c)(1)(D)(ii) accomplishes an immediate de facto exercise of eminent domain for which a Tucker Act remedy is not available (J.S. App. 33a-34a, 35a-36a). As a result, the district court had to consider whether the compensation provisions of Section 3(c)(1)(D)(ii) are constitutionally adequate to compensate Monsanto for the taking resulting from the

EPA's use of data submitted by Monsanto. But even if a Tucker Act remedy is available, the data submitter would first have to go through arbitration, and the situation would be the same as that discussed under the assumption that the data use and compensation provisions are valid. The constitutionality of compulsory arbitration would be ripe now because of the lack of judicial review later and because the compulsory arbitration would, in the meanwhile, inflict the very harm Monsanto seeks to avoid.

This situation is entirely unlike the situation in <u>Babbitt v. United Farm Worker</u>

Nat'l Union, 442 U.S. 289 (1979), upon which the EPA so strongly relies. In that case waiting until the arbitration had been completed could make the issues more ripe because the arbitration in <u>Babbitt</u> would be reviewable. In contrast to <u>Babbitt</u>, here the issues will not be made more ripe by waiting for an

tially nonreviewable. Moreover, in <u>Babbitt</u> the challenged compulsory arbitration provisions could not have any effect until there had been a strike or boycott which was restrained by a ten-day restraining order, none of which, had occurred. Monsanto has already received offers to compensate; thus, in contrast to <u>Babbitt</u>, all the prerequisites for compulsory arbitration have been fulfilled. Here the constitutionality of compulsory arbitration is ripe for review.

# 2. THE COMPULSORY ARBITRATION IS UNCONSTITUTIONAL BECAUSE IT VIOLATES DUE PROCESS GUARANTEES OF THE FIFTH AND FOURTEENTH AMENDMENTS

The Supreme Court has held compulsory arbitration unconstitutional as a means of settling labor disputes in packing plants, Chas. Wolff Packing Co. v. Court of Industrial Relations, 262 U.S. 522 (1923), authored by

Mansas, 264 U.S. 286 (1924), authored by Justice Brandeis. These cases held that in the absence of a compelling national emer= gency, as in Wilson v. New, 243 U.S. 332 (1917), or the exercise of the war powers as in Block v. Hirsh, 256 U.S. 135 (1921), the imposition of compulsory arbitration to resolve private disputes violated the due process guarantees of the Fifth and Fourteenth Amendments.

3. THE COMPULSORY ARBITRATION IS UNCONSTITUTIONAL BECAUSE IT VESTS JUDICIAL POWER IN TRIBUNALS NOT CREATED UNDER ARTICLE III OF THE CONSTITUTION

Northern Pipeline Construction Co. v. Marathon Pipe Line Co., 458 U.S. 50 (1982) is the controlling case for any discussion of Article III. The EPA understandably relegates it to a footnote (EPA Br. 49, n. 35) because it shows that, on any analysis, FIFRA Section 3(c)(1)(D)(ii) violates Article III.

Northern Pipeline rejected the proposition that the bankruptcy courts could have been constituted, consistent with Article III, as legislative courts, because legislative courts are limited to three narrow situations -- territorial courts, courts martial and courts adjudicating public rights -- and bankruptcy courts satisfy none of these. Northern Pipeline, 458 U.S. at 63-76. Similarly, an arbitration obviously doesn't qualify as a territorial court or a court martial, nor does an arbitration adjudicate public rights, since these "must at a minimum arise 'between the government and others'", Northern Pipeline, 458 U.S. at 69, quoting Ex Parte Bakelite Corp., 279 U.S. 438 (1929), whereas the liability of one individual to another is a matter of private rights. Private rights disputes, such as those present both in Northern Pipeline and in the instant case, lie at the core of the historically

recognized judicial power, Northern Pipeline, 458 U.S. at 69-70, citing Crowell v. Benson, 285 U.S. 22, at 51 (1932).

Northern Pipeline also rejected the proposition that, given the existence of a right to appeal to an Article III court, the bankruptcy courts are permissible as fact-finding adjuncts to Article III courts. The bankruptcy courts were not in any sense "adjunct" to Article III courts because the Bankruptcy Act did not reserve the essential attributes of the judicial power to Article III tribunals, Northern Pipeline, 458 U.S. at 77-78.

On the one hand, <u>Crowell v. Benson</u> upheld a specialized agency as a fact-finding adjunct to the Article III courts where the statute prescribed a mandatory schedule of compensation, the agency was limited to determining questions of fact as to the circumstances,

nature, extent and consequences of an employee's injury, and every compensation order was appealable to an Article III court which had the power to enforce it or set it aside depending on whether it was in accordance with law and supported by the evidence. Northern Pipeline, 458 U.S. at 78. On the other hand, United States v. Raddatz, 447 U.S. 667 (1980), upheld the 1978 Federal Magistrates Act which permitted an Article III court to refer certain pretrial motions and fact-finding functions to a magistrate whose proposed findings and recommendations were subject to review in the Article III court. Northern Pipeline, 458 U.S. at 79. These cases establish that, consistent with Article III, Congress may set up fact-finding adjuncts to Article III Courts either (a) where the agency has a very narrow and specialized fact-finding function within its area of expertise, does not recommend conclusions of law, promulgates

an award which is not self-enforcing and is subject to review by an Article III court to determine if an award is in accordance with the law and the findings are supported by the evidence, or (b) where the agency has a broad and generalized fact-finding function, recommends conclusions of law, promulgates a proposed order which is not self-enforcing and is subject to review by an Article III court.

Northern Pipeline held that the Bankruptcy Act violated Article III because it
allowed the bankruptcy courts to exercise
plenary jurisdiction over claims by or
against the debtor and to promulgate selfenforcing orders subject to review only under
the deferential "clearly erroneous" standard.
The bankruptcy courts could not qualify as
fact-finding adjuncts because the scope of
review was too narrow given the breadth of
their judicial power. A fortiori, compulsory
arbitration under FIFRA Section 3(c)(1)(D)(ii)

violates Article III because it grants all of the attributes of judicial power to arbitrators, reserving virtually nothing to the Article III courts. There is essentially no judicial review because Section 3(c)(1)(D)(ii) says:

[T]he findings and determination of the arbitrator shall be final and conclusive, and no official or court of the United States shall have power or jurisdiction to review any such findings and determination, except for fraud, misrepresentation, or other misconduct by one of the parties to the arbitration or the arbitrator where there is a verified complaint with supporting affidavits attesting to specific instances of such fraud, misrepresentation, or other misconduct. (Emphasis supplied)

This extremely narrow scope of review is even more restrictive than the scope of review found to be insufficient in Northern Pipeline. Yet within their office, the arbitrators' powers here are at least as broad as those of the bankruptcy judges in Northern Pipeline.

According to the statute, the arbitrators are to be chosen from the roster of the Federal Mediation and Conciliation Service ("FMCS"). They would have to decide all questions of law involved in the dispute, including the proper measure of compensation, the applicable statute of limitations, the applicablity of doctrines of waiver, laches, estoppel, work product and attorney-client privilege, the proper venue for the proceeding, the proper scope of discovery and admissibility of evidence. And the legal issues they decide are completely exempt from judicial review. They would also have to decide all issues of fact involved in the dispute, including precisely what studies should be compensible (including the contents, protocols and results of the studies), the cost of the data, the data user's reasonable share of the cost of the data (taking into account the exclusive use period under Section 3(c)(1)(D) (ii), the data submitter's other uses for the data and others who have or will share in the cost of the data), the method of payment (possibly including a reasonable royalty, see H.R. Rep. 94-479 (Agriculture) p. 65), the qualifications of experts, the credibility of witnesses and the appropriate provisions of protective orders. And the factual issues they decide are also completely exempt from judicial review. On the very matter in issue, that of compensation, the arbitrators could choose not to take into account the factors just mentioned, and nevertheless their decision is simply not reviewable.

The arbitrator's decision is self-enforcing because Section 3(c)(1)(D)(ii) provides that, "without further hearing," the subsequent data user's application shall be denied, or its registration shall be cancelled, if the Administrator determines that the subsequent data

user has failed to comply with the terms of an arbitration decision.

In short, Section 3(c)(D)(1)(ii) confers on the arbitrators, with virtually no judicial review, the plenary duties of a judge with no guidelines or constraints, presiding over a lawsuit from first to last. There is no meaningful sense in which the arbitrators are "adjuncts" to an Article III court.

Compulsory arbitration under FIFRA Section 3(c)(1)(D)(ii) is also unconstitutional under the analysis used by the Northern Pipeline dissenters. The dissenters also concluded that this Court retains the final word on how, consistent with Article III, Congress may balance competing constitutional values and legislative responsibilities, Northern Pipeline, 458 U.S. at 113. In striking that balance, the most critical factor to the dissenters is the presence (and, presumably, the scope) of review by an Article

III Court, Northern Pipeline, 458 U.S. at 115. Even on the dissenters' view, compulsory arbitration under Section 3(c)(1)(D)(ii) is unconstitutional because, as just discussed, review by the Article III Courts is virtually non-existent. The lack of judicial review is especially pernicious given the complete absence of standards for determining compensation, to which we now turn.

# 4. THE FIFRA ARBITRATION PROVISIONS ARE UNCONSTITUTIONALLY VAGUE

FIFRA Section 3(c)(1)(D)(ii) contains absolutely no standards for determining compensation and, because the judicial review is virtually non-existent, there is no possibility that standards can ever be developed.

The EPA (EPA Br. 48) and PPG Industries as Amicus Curiae (PPG Br. 6-11) are correct in stating that Congress intended compensation to be based on "a sharing of the governmentally

required <u>cost</u> of producing the test data."

<u>Chevron Chemical Co. v. Costle</u>, 641 F. 2d 104,

109 (3rd Cir. 1981), <u>cert</u>. <u>denied</u> 452 U.S. 961

(1981) (emphasis supplied).

The legislative history of FIFRA establishes that compensation was intended to be based on a sharing of costs. This has been the consistent standard ever since 1972, as is clearly set forth in the legislative history of the 1972, 1975 and 1978 amendments. The 1978 amendments are at issue in the case at bar. See S. Rep. No. 95-334 (Agriculture, Nutrition and Forestry), p. 4, "This bill will solve the problems by clearly defining the limits of trade secrets while . . . recognizing . . . the need for cost sharing among registrants." (emphasis supplied), p. 8, "The Subcommittee . . . accepted the provisions in S. 1678 . . . for binding arbitration where the parties cannot agree as to the equitable sharing of the costs," (emphasis

supplied); p. 31, "It [S. 1678] . . . keys the amount of payment by subsequent registrants to the cost of developing data necessary for governmental approval," (emphasis supplied); p. 95, "The sharing of the costs shall be on an equitable basis," (emphasis supplied); and p. 109, "we favor mandatory licensing of data with opportunity for sharing of data costs through compensation provisions," (emphasis supplied). See also, and 123 Congressional Record - Senate (1977) p. 25706," [The statutory scheme] protects the data developer's right to recover his data generation costs," (emphasis supplied). Under the 1972 and 1975 amendments, both of which also provided for mandatory licensing with compensation but without compulsory arbitration, the standard of compensation was also the equitable sharing of costs. Concerning the 1972 amendments, see S. Rep. No. 92-838 (Agriculture and Forestry), reprinted in 1972 U. S. Code Cong. & Ad. News,

p. 3993, at p. 4025, "The Agriculture Committee provision would not preclude other researchers from making their own similar tests or sharing by agreement in the costs and results of research done by others," (emphasis supplied); p. 4034 "[T]his provision is likely to result in equitable sharing of research costs. There would be little reason for duplicate testing if a second registrant could share in the test data of the first by paying a part of the cost. And there would be little reason for the first registrant nor recouping a part of his cost in this manner, since if he does not the second registrant can do his own testing," (emphasis supplied); p. 4089, "The substitute retains the exclusive use of data provision recommended by this Committee; but provides in addition for a mandatory licensing system under which permission to use test data in return for a reasonable share of the cost of producing the data would be required,"

(emphasis supplied); and p. 4092, "Thus it was decided that fairness and equity require a sharing of the governmentally required cost of producing the test data used in support of an application by an applicant other than the originator of such data," (emphasis supplied). 118 Congressional Record - Senate (September 26, 1972) p. 32257 (same as 1972 U.S. Code Cong. & Ad. News p. 4089, above) and p. 32258 (same as 1972 U.S. Code Cong. & Ad News, p. 4092, above) and Conf. Rep. No. 92-1540 reprinted in 1972 U. S. Code Cong. & Ad. News, p. 4130, at p. 4132, "The conferees concluded that the Administrator is in the best position to determine the proper amount of reasonable compensation for producing the test data that should be accorded the originator of such data," (emphasis supplied). Concerning the 1975 amendments, S. Rep. No. 94-452 (Agriculture and Forestry) p. 10, "As developed more fully in the Committee reports accompanying

the 1972 amendments, this provision was added to provide for equitable sharing among industry members of the cost of producing data necessary to obtain or continue a registration under the Act," (emphasis supplied).

The administrative interpretation of FIFRA when, prior to the 1978 amendments, compensation was determined by the EPA, also establishes that compensation was intended to be based on a sharing of cost. Ciba-Geigy Corp. v. Farmland Industries, Inc., FIFRA Comp. Dkt. Nos. 33, 34 and 41, slip opinion at p. 46 (Aug. 19, 1980), final order issued by the judicial officer (April 30, 1981), affirmed by the Administrator (July 28, 1981); Union Carbide Agricultural Products Co. v. Thompson-Hayward Chemical Co., FIFRA Comp. Dkt. No. 27, slip opinion at p. 21 (July 13, 1982): "But it would appear that it was only the incremental cost of obtaining a registration that Congress appears to have been concerned about,

and the desirability of neutralizing any adverse effect on research and development which would be caused if the entire testing cost were imposed on the first registrant, emphasis supplied.

The judicial interpretation of FIFRA also establishes that compensation was intended to be based on a sharing of costs. Chevron Chemical Co. v. Costle, 641 F.2d 104, 109 (3rd Cir. 1981), cert. denied 452 U.S. 961 (1981); Amchem Products, Inc. v. GAF Corp. 594 F.2d 470, 481 (5th Cir. 1979), modified, 602 F.2d 724 (5th Cir. 1979): "It was never the intent of Section 3(c)(1)(D)(ii) to provide more than an equitable sharing of research costs,") (emphasis supplied); Chevron Chemical Co. v. Costle, 443 F. Supp. 1024, 1028 n.2. (N. D. Cal. 1978) [purpose of data compensation was] "saving the cost of duplicative test data,") (emphasis supplied); Mobay Chemical Corp v. Costle, 12 Env't Rep. Cas. (BNA) 1572, 1578 (W.D. Mo. 1978), appeal dismissed for want of jurisdiction, 439 U.S. 320 (1979) (per curiam): "[T]he Congressional concern in adopting the original 3(c)(1)(D) was for maximum allocation of resources in the public interest by preventing the necessity of costly duplicative testing in order to produce governmentally-mandated data without thereby casting the entire burden upon the party first to meet the government requirements by producing or submitting that data," (emphasis supplied).

Mobay also establishes that the courts, consistent with the congressional intent, have expressly rejected the value theory. "The protection afforded by Section 3(c)(1)(D) extends only to compensation for producing test data used in the registration process, and not to the ultimate economic or commercial benefits which may flow from the registration itself," (emphasis supplied.) Mobay Chemical

Corp. v. Costle, 447 F. Supp. 811, 834 (W.D. Mo. 1978) modified, 517 F. Supp. 252 (W.D. Pa. 1981), aff'd. sub nom. Mobay Chemical Corp. v. Gorsuch, 682 F.2d 419 (3rd Cir. 1982) cert. denied, 103 S.Ct. 343 (1982).

Despite the seemingly clear legislative history and administrative and judicial interpretation, due to the fact that actual language adopted by Congress contains no standards, such language has already led to an award that bears no rational relation to cost. In the only arbitration under Section 3(c)(1) (D)(ii) ever completed, the claimant was awarded a sum equal to more than twenty times the data user's fair share of cost of producing the data. The arbitration respondent in the Stauffer/PPG arbitration claimed the compensation should be based on cost sharing. The arbitration claimant, relying on the absence of standards in the statute, claimed compensation on a "value" theory based on the

alleged "economic benefit" to PPG of "being able to start marketing its butylate some five years earlier than it could have without reliance on Stauffer's data," page 12 of the Award, a copy of which is attached to the Complaint in PPG Industries, Inc. v. Stauffer Chemical Company, Case No. 83-1941, United States District Court for the District of Columbia. The Award charged PPG with \$1.46 million as its one-half share of Stauffer's historical costs, which were \$2.93 million expressed in 1983 dollars. However, the Award in Stauffer adopted the "value" theory, which resulted in an award against PPG which one of the attorneys for Stauffer, has said has a present value of over \$30 million. This statement was made during the October 11, 1983 hearing in Sathon, Inc. v. American Arbitration Association and Zoecon Corporation, Case No. 83 C 6019, United States District Court for the Northern District of

Illinois.) Thus, the value theory produces a windfall for the data submitter and erects a barrier to competitors' entry into the market-place, both of which are contrary to Congress' intent in enacting FIFRA Section 3(c)(1)(D)(ii).

The foregoing example is precisely the sort of standardless, unrestrained and unreviewable discretion that renders the statute unconstitutionally vague.

# 5. THE COMPULSORY ARBITRATION IS UNCONSTITUTIONAL BECAUSE OF ABSENCE OF THE RIGHT TO A JURY TRIAL

The Seventh Amendment preserves the right to a jury trial in suits at common law. The compulsory arbitration provisions of FIFRA are also unconstitutional because they deny the parties their Seventh Amendment right to a jury trial. The data submitter's claim for compensation, if any, is a monetary claim

in the nature of an action of general assumpsit at common law, Thomas v. Matthiesson, 232 U.S. 221, 235 (1914); Archawski v. Hanioti, 350 U.S. 532, 534 (1956); 7 C.J.S., "Assumpsit, Action of", §§ 3 and 10.b; for which the right to a jury trial is preserved, Dairy Queen, Inc. v. Wood, 369 U.S. 469 (1962); Moore, Lucas and Wicker, 5 Moore's Federal Practice (1982 Ed.), par. 38.11[5]. The parties to a FIFRA data compensation dispute have the right to have a jury decide (1) the data for which compensation is to be paid, (2) the total cost of such data, (3) the data user's reasonable share of the cost of the data.

## 6. THE COMPULSORY ARBITRATION IS UNCONSTITUTIONAL BECAUSE OF THE ABSENCE OF SAFEGUARDS FOR PROCEDURAL DUE PROCESS

When governmental agencies adjudicate or make binding determinations which directly

affect legal rights, it is imperative that those agencies use the procedures that have traditionally been associated with the differing types of proceedings. Whether the Constitution requires a specific right in a specific proceeding depends on the private interest implicated, the nature of the right involved (including the risk of an erroneous determination that can be avoided by the added procedural safeguard), the nature of the proceeding and the possible burdens on that proceeding including costs that the additional procedures would involve. Hannah v. Larche, 363 U.S. 420, 422 (1960); Mathews v. Eldridge, 424 U.S. 319, 335 (1976).

Complusory arbitration under FIFRA Section 3(c)(1)(D)(ii) purports to decide the original data submitter's claim for compensation from the subsequent data user for the use by the Administrator of data submitted by the former in support of the

'atter's application. This proceeding is clearly an adjudication, since it decides the liability of one party to another party, Northern Pipeline, 458 U.S. at 70. Compulsory arbitration denies the parties' Fifth Amendment right to due process of law because (a) compulsory arbitration is offensive to the Fifth Amendment, as seen above, absent some form of national emergency or the exercise of the war powers, (b) the parties have the right to an adjudication by an Article III court, (c) the parties have the right to compulsory process for obtaining evidence in their favor, and (d) the party against which the claim is made has the right to have the adjudication held in an area with which it has at least a minimum level of contacts. These procedural safeguards are rules of fair play which have become associated with proceedings which adjudicate monetary claims between private parties, and none of these safeguards impose an undue burden on the proceeding. In considering the possible burden the procedural safeguards impose on the proceeding, it is appropriate to also consider the burden the proceeding imposes on the parties. The burden of the proceeding can itself be devastating, and with substantial anticompetitive effects.\*

The Article III issue previously discussed is not merely a question of separation of powers. It also affects the right to have an

<sup>\*</sup>Sathon is literally engaged in struggle for its very survival against a competitor, Zoecon Corporation, whose sales are over 160 times Sathon's and the sales of whose parent are approximately 10,000 times Sathon's, and against a claim for 12 to 20 times Sathon's annual sales, Affidavit of W. Eric Ashton attached as Exhibit A to Memorandum in Support of Alternative Motion for Preliminary Injunction filed in Sathon, Inc. v. American Arbitration Association and Zoecon Corporation, U.S. District Court for the Northern District of Illinois, Case No. 83 C 6019.

adjudication in a constitutionally guaranteed forum.

The failure of compulsory arbitration under Section 3(c)(1)(D)(ii) to give the parties the right to compulsory process for obtaining evidence in their favor denies due process because this procedural right is universally allowed in proceedings to adjudicate monetary claims. Most importantly, compulsory process must be available to require the EPA to identify the data actually required and/or relied upon in support of the application.

The FIFRA arbitration procedures are also unconstitutional in that there is no standard for determining the locale of the arbitration. The Due Process clause of the Fifth Amendment requires the same interpretation as the Due Process Clause of the Fourteenth Amendment, namely to require that the contacts of the nonconsenting party with the forum "must be

such that maintenance of the suit 'does not offend traditional notions of fair play and substantial justice.' World-Wide Volkswagen Corp. v. Woodson, 444 U.S. 286, 292, (1980). Yet the nonconsenting arbitrant can be forced into a locale with which it has absolutely no contacts, ties or relations. This denies due process. Woodson, 444 U.S. at 294.

7. THE FEDERAL MEDIATION AND
CONCILIATION SERVICE WAS WITHOUT
AUTHORITY TO DELEGATE FIFRA ARBITRATIONS
TO THE AMERICAN ARBITRATION ASSOCIATION

With respect to compulsory arbitrations, FIFRA Section 3(c)(1)(D)(ii) provides:

- (1) That the request for arbitration shall be made of the Federal Mediation and Conciliation Service;
- (2) That the arbitrators shall be selected from the roster maintained by such Service; and
- (3) That the procedure and rules of such Service shall be applicable,

- (i) to the selection of the arbitrator, and
  - (ii) to such arbitration proceedings.

The Federal Mediation and Conciliation Service (FMCS) is an independent governmental agency. 29 U.S.C. 172(a). The appointment of a roster of conciliators and mediators is a regulatory function specifically included in the statute creating FMCS. 29 U.S.C. 172(b); 29 C.F.R. 1404.4-.6 (1983).

The procedure for the selection of arbitrators and the arbitration proceedings are likewise within the regulatory function of the agency. 29 C.F.R. 1404.10-17 (1983). The power to delegate is also specifically set forth in the statute. "The Director may by order, subject to revocation at any time, delegate any authority and discretion conferred upon him by this chapter to any regional director, or other officer or employee of the Service". 29 U.S.C. 172(c). No authority

exists in the statute for the FMCS to delegate any of its functions to any other person or organization. Under the general principle of statutory construction that <u>inclusio unius est</u> exclusio alterius, no other delegation may be made.

In its final regulations on Arbitration of Pesticide Data Disputes, published at 45 Fed. Reg. 55394 et seq. (August 19, 1980) (codified at 29 C.F.R. Part 1440 and Appendix) the FMCS delegated the whole of these functions to the American Arbitration Association. The final regulations provide:

- (1) "For this purpose, the Service will utilize as its roster of arbitrators the roster of commercial arbitrators maintained by The American Arbitration Association..." Id.
- (2) "The FIFRA arbitration rules of the AAA will be the rules of procedure to be

followed for arbitration of pesticide data compensation disputes. Id.

The above cited final rule purports to be issued "under the authority of the Federal Insecticide, Fungicide, and Rodenticide Act," but no authority for such a delegation exists in said Act.

The delegation of its regulatory function by the FMCS to the AAA was in contravention of the applicable statutes and therefore illegal.

Cudahy Packing Co. v. Holland, 315 U.S. 357, (1942). By its complete substitution of the AAA for itself, the FMCS has effectively rewritten the statute. It is elementary that administrative agencies may not re-write the statutes of Congress.

8. THE CHALLENGED PROVISIONS
OF THE STATUTE ARE SEVERABLE
FROM THE PROVISIONS FOR DATA
USE AND DATA COMPENSATION

## (1) General Principles of Severability

The test of severability, as stated in Champlin Refining Co. v. Corporation Commission, 286 U.S. 210, 234-235 (1932); Buckley v. Valeo, 424 U.S. 1, 108 (1976); and INS v. Chadha, \_\_\_\_ U.S. \_\_\_, 77 L.Ed.2d 317, 334 (June 23, 1983), is this:

Unless it is evident that the Legislature would not have enacted those provisions which are within its power, independently of that which is not, the invalid part may be dropped if what is left is fully operative as a law.

This test is particularly appropriate because the severability clause in the challenged statute in <u>Champlin</u>, quoted in footnote 1 at 286 U.S. page 223, is very similar to FIFRA's severability clause, 7 U.S.C. 136x.

Applying this test to FIFRA Section 3(c)(1)(D)(ii), we find that the compulsory arbitration provisions are not severable from the provisions limiting judicial review, but both are severable from the rest of the statute.

## (2) The Challenged Provisions of the Statute are Severable from the Rest of the Statue

Prior to the 1978 amendments, FIFRA Section 3(c)(1)(D) provided for subsequent applicants' use of data previously submitted by others and for an offer of compensation by the subsequent data user to the original data submitter, Pub. L. 92-516, 86 Stat. 973 (October 21, 1972), and reenacted in 1975, Pub. L. 94-140, 89 Stat. 751 (November 28, 1975). The offending provisions for compulsory arbitration and the offending provisions limiting judicial review may have been added in 1978 because the pesticide data compensation disputes were said to impose a burden on the EPA, Chevron Chemical Co. v. Costle, 641 F.2d. 104, 111 (3rd Cir.), cert. denied 452 U.S. 961 (1981). Thus, striking down compulsory nonreviewable arbitration would be consistent with Congress' presumed intent to relieve the EPA of any such burden.

The non-offending provisions of the statute are grammatically distinct from the offending provisions. Striking the offending provisions of Section 3(c)(1)(D)(ii) (from and including "The terms and amount of compensation may be fixed . . . " to and including " . . . allow fifteen days from the date of delivery of the notice for the affected person to respond.") would leave the non-offending provisions operative. In the absence of the offending compulsory arbitration provisions and the offending provisions limiting judicial review, the Administrator could still use the data, the requirement of an offer to pay compensation would still exist, and the data submitter could bring suit in any court of competent jurisdiction.

(3) The Challenged Compulsory Arbitration Provisions are not Severable from the Challenged Prohibitions on Judicial Review

In the 1978 amendments to FIFRA, Congress enacted both the compulsory arbitration provisions and the provisions limiting judicial review. The compulsory arbitration provisions are not grammatically distinct from the provisions limiting judicial review, since one sentence contains provisions relating to both. Furthermore, there is absolutely nothing to indicate the type of judicial review Congress would have enacted in place of the offending provisions limiting judicial review. Moreover, there is no evidence in the legislative history to suggest that Congress intended to enact the compulsory arbitration provisions independently of the provisions limiting judicial review, Dorchy, 264 U.S. at 290, Champlin, 286 U.S. at 234-35, Buckley, 424 U.S. at 108, Chadha, 77 L.Ed.2d at 334.

The 1978 amendments were enacted by Pub. L. 95-396, 92 Stat. 819. (September 30, 1978) Although this law was derived most immediately from Senate Bill S. 1678, its legislative geneology includes two House bills, H.R. 7073 and H.R. 8681. The text of H.R. 7073, contained in House Report No. 95-334 (Agriculture), dated May 16 and June 1, 1977, does not contain any language related either to compulsory arbitration or to limitations on judicial review, see especially pp. 12-15. The text of S. 1678, particularly the part found at pages 129 and 130 of the Senate Report No. 95-334 (Agriculture, Nutrition and Forestry), dated July 6, 1977, contains language similar or identical to the language finally enacted, including both the compulsory arbitration provisions and the provisions limiting judicial review. Concerning H.R. 8681, page 3 of House Report No. 95-663 (Agriculture), dated October 5, 1977,

also contains language similar to the language finally enacted and also including both challenged provisions. Pages 3 and 4 of the conference report on S. 1678, Senate Conf. Rep. No. 95-1188, dated September 12, 1978, contains the final language, including both the challenged provisions. In short, there is no evidence of legislative intent to enact the compulsory arbitration provisions independently of the provisions limiting judicial review. Quite to the contrary, wherever one was proposed, so was the other.

Accordingly, although the unconstitutionality of FIFRA Section 3(c)(1)(D)(ii) can be cured by striking down the provisions for compulsory arbitration and those limiting judicial review, even assuming the compulsory arbitration provisions are constitutional alone, or would be made so if there were adequate provision for judicial review, the

statute cannot be cured by merely striking down the provisions limiting judicial review.

(4) The Partial Invalidity of the 1978 Amendments Revives the Prior Provisions for Dispute Resolution by the EPA

It appears that invalidity of the compulsory arbitration provisions and the provisions restricting judicial review, which were already shown to be separable from the rest of the 1978 Amendments, will revive the dispute resolution procedure of the prior law. It has been held that if a portion of an act which is an amendment of another act already in force is invalid and is inseparable from the remainder of the amendment, the entire amending act may be declared inoperative without in any way affecting the original act. (16 Am. Jr.2d, Constitutional Law, Section 263) would be consistent with Congress' expressed intent under the 1975 Amendments to have pesticide compensation disputes resolved by an EPA Administrative law judge, which comports with Article III and the Fifth Amendment, and which would return compensation dispute resolution to the administrative law judges who had previously developed expertise in the area and are subject to review both by the Administrator and by the Article III courts.

#### III.

#### CONCLUSION

For the reasons set forth above, Sathon prays that the Court find the constitutionality of the provisions requiring compulsory arbitration and limiting judicial review to fraud, misrepresentation and other misconduct contained in FIFRA Section 3(c)(1)(D)(iii) is ripe for review, and that the Court hold these provisions to be unconstitutional.

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Office - Supreme Court, U.S. FILED JAN - 19 1984

## IN THE

# Supreme Court of the United States

OCTOBER TERM, 1983

WILLIAM D. RUCKELSHAUS, ADMINISTRATOR, UNITED STATES ENVIRONMENTAL PROTECTION AGENCY. Appellant,

MONSANTO COMPANY,

Appellee.

On Appeal From The United States District Court For The Eastern District Of Missouri

BRIEF OF SDS BIOTECH CORPORATION. ATLANTIC & PACIFIC RESEARCH, INC., AND PBI-GORDON CORPORATION AS AMICI CURIAE IN SUPPORT OF APPELLEE

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# TABLE OF CONTENTS

	Page
TABLE OF AUTHORITIES	iii
INTEREST OF AMICI CURIAE	1
SUMMARY OF ARGUMENT	4
ARGUMENT	7
I. FIFRA'S MANDATORY DATA LICENSING PROVISIONS TRANSFER A MAJOR ECONOMIC BENEFIT TO A NARROW CLASS OF FOLLOW-ON REGISTRANTS WITHOUT SIGNIF ICANTLY PROMOTING COMPETITION	V .
A. The Pesticide Industry Consists Of Three Classes Of Companies, Two Of Which Play A Major Direct Or Indirect Role In The Development Of Research And Test Data	
B. Firms That Develop And Register New Pesti- cides Do So At Great Expense And Economic Risk	10
C. Mandatory Licensing Transfers A Major Un- earned Benefit To A Small Class Of Follow-On Registrants	1 12
D. Mandatory Data Licensing Is Not Necessary To Ensure Competitive Pesticide Prices	13
II. THE MANDATORY DATA LICENSING SCHEME IS AN UNCONSTITUTIONAL TAKING OF DATA SUBMITTERS PROPERTY FOR PRIVATE PURPOSES AND WITHOUT JUST COMPENSATION	,
A. Data Submitters Have Protected Property In- terests In Their Registration Data And The Mandatory Licensing Provisions Effect A Tak- ing Of That Property	
B. The Taking Of Data Developers' Property Is For Private Purposes And Is Therefore Uncon- stitutional	
A taking for private purposes is unconstitutional	19
2. The private purpose of the challenged provisions is clear from their operation and effect	1

# **Table of Contents Continued**

	Page
C. Even If The Taking Were For Public Purposes, It Would Be Unconstitutional Because Data Submitters Do Not Receive Just Compensa- tion	24
III. THE COURT NEED NOT DECIDE AT THIS TIME WHETHER A DECISION IN FAVOR OF APPELLEE MUST BE RETROACTIVELY APPLIED, AND SHOULD NOT FORECLOSE RETROACTIVE APPLICATION IN APPROPRIATE CASES	
Conclusion	30

# TABLE OF AUTHORITIES

CASES:	Page
Armstrong v. United States, 364 U.S. 40 (1960)	27
Baltimore & Ohio Railroad v. United States, 298 U.S. 349 (1936)	24
Berman v. Parker, 348 U.S. 26 (1954) 20	), 21
Chevron Oil Co. v. Huson, 404 U.S. 97 (1971)	28
Ciba-Geigy Corp. v. Farmland Industries, Inc., FIFRA Comp. Docket Nos. 33, 34, and 41 (1980)	25
Cincinnati Bell Foundry Co. v. Dodds, 10 Ohio Dec. Reprint 154 (Super. Ct. 1887)	17
Dasho v. Susquehanna Corp., 461 F.2d 11 (7th Cir.), cert. denied, 408 U.S. 925 (1972)	28
Garrity v. New Jersey, 385 U.S. 493 (1967)	18
Gulf Offshore Co. v. Mobil Oil Corp., 453 U.S. 473 (1981)	27
Johnson v. Lehman, 679 F.2d 918 (D.C. Cir. 1982)	27
Kaiser Aetna v. United States, 444 U.S. 164 (1979)	7, 18
Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470 (1974)	5, 17
Lee v. Cercoa, Inc., 433 So.2d 1 (Fla. Dist. Ct. App. 1983)	17
Lefkowitz v. Turley, 414 U.S. 70 (1973)	18
Midkiff v. Tom, 702 F.2d 788 (9th Cir.), prob. juris. noted sub nom. Hawaii Housing Authority v. Mid- kiff, U.S, 104 S. Ct. 334 (1983)	20
Monongahela Navigation Co. v. United States, 148 U.S. 312 (1893)	5, 27
Mullins v. Andrus, 664 F.2d 297 (D.C. Cir. 1980)	27
Norton v. Shelby County, 118 U.S. 425 (1886)	28
Pennsylvania Coal Co. v. Mahon, 260 U.S. 393 (1922)	9. 20
St. Joseph Stock Yards Co. v. United States, 298 U.S. 38 (1936)	20
Sherbert v. Verner, 374 U.S. 398 (1963)	18
Speiser v. Randall, 357 U.S. 513 (1958)	18

# **Table of Authorities Continued**

	Page
Spevak v. Klein, 385 U.S. 511 (1967)	. 18
Stauffer Chemical Co. v. PPG Industries, Inc., Docke No. PPG Industries, Inc. 16-199-077-82 FIFRA (1983) (Birch, Smolka, and Vassil, Arb.)	1
Thompson v. Consolidated Gas Utilities Corp., 300 U.S.	
Thorpe v. Housing Authority, 393 U.S. 268 (1969)	. 27
Union Carbide v. Thompson-Hayward Chemical Co. FIFRA Comp. Docket No. 27 (1982)	25
Unistar Corp. v. Child, 415 So.2d 733 (Fla. Dist. Ct App. 1982)	17
United States ex rel. TVA v. Welch, 327 U.S. 546 (1946)	20
United States v. Generix Drug Corp., U.S, 103 S. Ct. 1298 (1983)	3 15, 16
United States v. Johnson, 457 U.S. 537 (1982)	
United States v. New River Collieries Co., 262 U.S. 34	
United States v. The Schooner Peggy, 5 U.S. (1 Cranch 103 (1801)	27
Usery v. Turner Elkhorn Mining Co., 428 U.S. 1 (1976)	26
Wearly v. FTC, 462 F. Supp. 589 (D.N.J. 1978), vacated on other grounds, 616 F.2d 662 (3d Cir.), cert. denied 449 U.S. 822 (1980)	21
Zweibon v. Mitchell, 606 F.2d 1172 (D.C. Cir. 1979), cert denied, 453 U.S. 912 (1981)	
STATUTES AND REGULATIONS:	
Federal Insecticide, Fungicide, and Rodenticide Act, 'U.S.C. §§ 136-136y (1982)	7
§ 3(e)(1)(D), 7 U.S.C. § 136a(e)(1)(D)	1, 26
§ 3(c)(2)(D), 7 U.S.C. § 136a(c)(2)(D)	
§ 6(b) and (d), 7 U.S.C. § 136d(b) and (d)	29
Federal Food, Drug, and Cosmetic Act,	
21 U.S.C. § 301 et seq. (1982)	
21 U.S.C. § 355	15

# **Table of Authorities Continued**

P	age
Ohio Rev. Code Ann. § 1333.51 (Page 1979)	17
21 C.F.R. § 314.1 (1983)	15
21 C.F.R. § 314.2 (1983)	16
40 C.F.R. § 162.9-8(a) and (b)(1983)	9
40 C.F.R. § 162.163(b)(2), 48 Fed. Reg. 34000, 34006	-
(1983)	26
40 C.F.R. Part 164 (1983)	29
LEGISLATIVE MATERIALS:	
123 Cong. Rec. 36000 (1977)	9
H.R. Rep. No. 511, 92d Cong., 1st Sess. (1971)	21
H.R. Rep. No. 566, 97th Cong., 2d Sess. (1982)	21
S. Rep. No. 838, 92d Cong., 2d Sess. (1972)	21
S. Rep. No. 334, 95th Cong., 1st Sess. (1977) .8, 11, 12	. 21
S. Rep. No. 551, 97th Cong., 2d Sess. (1982)	21
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Extension of the Federal Insecticide, Fungicide, and Rodenticide Act: Hearings Before the Subcomm. on Agricultural Research and General Legislation of the Senate Comm. on Agriculture, Nutrition, and Forestry, 95th Cong., 1st Sess. (1977)	13
Staff of Subcomm. on Administrative Practice and Procedure of Senate Comm. on the Judiciary, 94th Cong., 2d Sess., The Environmental Protection Agency and the Regulation of Pesticides (Comm. Print 1976).	21
MISCELLANEOUS:	
44 Fed. Reg. 27945 (1979)	23
47 Fed. Reg. 53192 (1982)	26
48 Fed. Reg. 2751 (1983)	16
48 Fed. Reg. 34000 (1983)	26
49 Fed. Reg. 508 (1984)	2

# **Table of Authorities Continued**

Page	
49 Fed. Reg. 509 (1984)	i
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Restatement of Torts § 757 (1939)	7
U.S. Environmental Protection Agency, Regulatory Impact Analysis: Data Requirements for Registering Pesticides Under the Federal Insecticide, Fungicide, and Rodenticide Act (1982) 7, 8, 9, 11, 12, 13	3
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### IN THE

# Supreme Court of the United States

OCTOBER TERM, 1983

No. 83-196

WILLIAM D. RUCKELSHAUS, ADMINISTRATOR,
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY,
Appellant,

V.

MONSANTO COMPANY,

Appellee.

On Appeal From The United States District Court For The Eastern District Of Missouri

BRIEF OF SDS BIOTECH CORPORATION, ATLANTIC & PACIFIC RESEARCH, INC., AND PBI-GORDON CORPORATION AS AMICI CURIAE IN SUPPORT OF APPELLEE

This brief is filed on behalf of SDS Biotech Corporation ("SDS"), Atlantic & Pacific Research, Inc. ("A&P"), and PBI-Gordon Corporation ("PBI") with the parties' consent.

#### INTEREST OF AMICI CURIAE

SDS, A&P, and PBI are, to varying degrees, engaged in the invention, manufacture, formulation, and distribution of pesticides. All three are therefore subject to the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. §§ 136-136y (1982) ("FIFRA"), including the mandatory data licensing provisions of Section 3(c)(1)(D), 7 U.S.C. § 136a(c)(1)(D). The operation of these statutory provisions has been fully

described by the parties. Like Monsanto Company, in whose support amici file this brief, amici have a substantial interest in affirmance of the ruling below that FIFRA's mandatory licensing provisions are unconstitutional.

SDS is a Delaware corporation, formed in 1983,¹ that invents, manufactures, and distributes pesticides. SDS depends on the fungicide chlorothalonil, which it invented, for over half of its sales and profits. SDS has spent millions of dollars over the last two decades to generate the data necessary to obtain its chlorothalonil registrations and maintain them in effect. If the decision below is not affirmed, SDS will lose its valuable property rights in these trade secret data.

Indeed, given the potential harm to SDS from the mandatory licensing provisions, SDS in 1979 prepared its own complaint challenging the constitutionality of those provisions. In view of SDS's complaint and the pendency of Monsanto's and similar cases, EPA agreed in June, 1979, in consideration of SDS's forbearance from seeking immediate injunctive relief, not to register pesticides containing chlorothalonil without thirty days' advance notice to allow SDS to protect its interests. However, under the challenged provisions, a follow-on registrant, Griffin Corporation ("Griffin"), obtained a chlorothalonil registration on the basis of SDS's data, without SDS's consent, without the notice required by the 1979 agreement, and to SDS's substantial detriment. EPA has initiated an administrative proceeding to consider cancelling that registration in light of the Agency's admitted breach of its agreement.<sup>2</sup>

<sup>&</sup>lt;sup>1</sup> Prior to SDS's formation, the pesticides now registered by SDS were registered by Diamond Shamrock Corporation. In July, 1983, SDS acquired all of Diamond's rights and interests in chlorothalonil, see infra, and certain other pesticides. Accordingly, this brief will use "SDS" to refer both to Diamond, with respect to events prior to formation of SDS, and to SDS with respect to events thereafter.

<sup>&</sup>lt;sup>2</sup> Notice of Intent to Hold a Hearing, 49 Fed. Reg. 508 (1984).

A&P is a small Florida corporation with yearly sales of \$750,000 to \$1 million. In terms of the pesticide industry it is extremely small and holds only one registration, for CYTEX. a plant growth regulator. A&P obtained its registration on the basis of its own data after several years of research. Within two years the data had been used, without A&P's consent, to approve registrations for at least two other companies. This unconsented use of A&P's data has damaged A&P's ability to obtain a return on its investment. Moreover, A&P believes that the follow-on registrations were for products that are not identical to A&P's. Without complete data on the specific products registered, it is doubtful whether EPA can assure the public that the follow-on products do not pose unreasonable risks to health and the environment. Although A&P has developed ideas for other new pesticides. FIFRA's failure to protect proprietary rights significantly impairs A&P's willingness and ability to engage in the risky, time-consuming, and costly process of developing new pesticides.

PBI is a Missouri corporation engaged in the formulation, distribution, and sale of pesticides. PBI is a member of the Pesticide Producers Association ("PPA"), but its interests lead it to file this brief on behalf of Monsanto and not, like PPA, in support of EPA. Although PBI does not engage in research to discover new pesticides, it always obtains a developer's consent before relying on the developer's data to support a registration application. In addition, PBI does conduct research intended to discover new uses for existing pesticides. New uses, like new pesticides, must be registered and supported by extensive research and test data, which are then available to follow-on registrants through mandatory licensing. Through its efforts, PBI acquires valuable information known only to it, which affords it a significant competitive advantage. The development of new uses for existing prod-

<sup>&</sup>lt;sup>3</sup> Brief of the Pesticide Producers Association, Drexel Chemical Company, Falls Chemicals, Inc., and Griffin Corporation as *Amici Curiae* ("PPA Br.").

ucts, like new products, benefits American agriculture and the consumer. A company's willingness to conduct this research and development depends not upon whether it is large or small—PBI is small with yearly sales of less than thirty million dollars—but upon whether it can earn an adequate return on its investment. Doing so is particularly difficult with respect to research on products already in the marketplace. On such products with no patent protection, trade secret protections afford the only competitive advantage for the innovating company. Only if this Court protects the proprietary rights acquired by the significant investment of time, effort, and money in the development of trade secret data can companies engaged in research and development obtain a return justifying the substantial risks involved.

Accordingly, amici file this brief to protect their property rights in their pesticide registration data, to respond to erroneous assertions in the PPA Brief, to which Griffin is a party, and to urge the Court not to accept the implicit invitation of other amici to foreclose retroactive application of an affirmance.

#### SUMMARY OF ARGUMENT

SDS, A&P, and PBI seek to bring to this Court a fundamentally different perspective from that offered by EPA and its supporting amici on how the issues in this case must be weighed. From reading the briefs of Appellant and its supporters, one would conclude that FIFRA is a statute intended primarily to regulate competition and only incidentally to protect public health and safety through the regulation of pesticides. To the contrary, as the legislative history of the statute overwhelmingly demonstrates, Congress' primary goal in FIFRA has been the development of a system of regulating and monitoring pesticides that will fully protect health and the environment. The very few provisions of the law that address competitive issues create a benefit solely for a handful of private companies, impair EPA's ability to protect health and safety, and serve no public purpose. It is in this context that the Court must scrutinize the challenged provisions of FIFRA.

I. Of the several thousand firms that sell pesticides, only forty or so, both large and small, attempt to develop and manufacture new pesticides and generate the data necessary for their registration. These efforts typically require an extraordinary investment of time and money, and a willingness to undertake substantial risks of failure.

Most of the roughly 3,300 firms that sell finished pesticide products rely on a FIFRA provision that obligates them to purchase the basic pesticidal chemicals from manufacturers in order to formulate end-use products, rather than manufacture those active ingredients themselves. Sales of registered active ingredients to such "formulators" occur only after arm's-length negotiations and a completed compensation arrangement. These arrangements enable manufacturers to recover some of the costs of developing the chemicals. The formulators need not submit or cite data on the purchased active ingredients, although they may be required to submit or cite certain additional data to register their end-use products.

There remains only a narrow third class of firms-roughly ninety manufacturers that obtain follow-on registrations and avoid virtually all data submission requirements—about which this case is concerned. Relying on the mandatory licensing provisions, they receive all the benefits of new pesticide development and data generation without having to conduct such research themselves or to enter into voluntary, arm's-length negotiations with developers. Compensation for the developers, if any, may not occur until years after a follow-on registrant has entered the market, and does not justly compensate the developer. It is these follow-on firms to which mandatory licensing directs a major private benefit, at the expense of the original pesticide manufacturers and data developers and the formulators that share in development costs through their purchases of active ingredients. No substantial public benefit is produced by thus favoring this small group, since pesticide prices already are limited by other factors, including competition among different types of products.

II. The FIFRA mandatory licensing scheme permitting use of *amici's* trade secret data is clearly a taking of their property. It destroys the essential benefit conferred by ownership of a trade secret, *i.e.*, the competitive advantage that results from the ownership and development of such data.

That taking is unconstitutional because it is for private purposes. Judicial analysis of whether the taking is for private or public purposes cannot rest solely on Congress' statements of its purposes because those statements are inconsistent: the allegedly "public" purposes of mandatory licensing undermine FIFRA's primary objective of protecting health and the environment. Accordingly, the Court must look to the actual operation of the statute to determine its purpose and effect. Scrutiny of the challenged provisions reveals that they benefit only a small class of private parties for whom the prerequisites to the sale of pesticides—prerequisites created by Congress to protect health and the environment—are waived. This benefit deprives EPA of health and safety data that otherwise would be available, and confers little or no public benefit in the form of increased competition. In short, mandatory licensing is the reverse of a constitutional taking, in which there is a public purpose with incidental private benefit. Here there is a private purpose with only incidental, if any, public benefit.

Even if this Court were to find a public purpose, the taking nevertheless would be unconstitutional, because just compensation for data developers is unavailable.

III. Amici in support of Appellant have referred to the possible effect of an affirmance on previously issued pesticide registrations. Such references implicitly invite the Court to address the question of retroactive application of its ruling. The Court need not reach that question to decide this case and should not consider the issue of retroactivity in the absence of a factual record on which to base its review. The general rule, which favors retroactivity unless a decision clearly breaks with prior law relied on by litigants and unless retroactivity would

retard the purposes of the new decision or create inequities, clearly requires a factual inquiry into the circumstances of a case in which retroactive application is sought. Such an inquiry may find retroactivity to be more appropriate in some cases than others. The Court therefore should not attempt to anticipate the different circumstances in which the issue could arise, and should not foreclose retroactive relief in an appropriate case with a record on that issue.

#### ARGUMENT

I. FIFRA'S MANDATORY DATA LICENSING PROVI-SIONS TRANSFER A MAJOR ECONOMIC BENEFIT TO A NARROW CLASS OF FOLLOW-ON REG-ISTRANTS WITHOUT SIGNIFICANTLY PROMOTING COMPETITION.

FIFRA is unique among federal health and safety statutes in the favor it gives to one small segment of the regulated community. Mandatory data licensing grants a major unearned economic benefit to a few follow-on registrants, at the expense of those that develop, evaluate, and submit safety data and those that properly compensate the data submitters.

A. The Pesticide Industry Consists Of Three Classes Of Companies, Two Of Which Play A Major Direct Or Indirect Role In The Development Of Research And Test Data.

A recent EPA study found that approximately 130 firms in the United States produce basic pesticide chemicals.<sup>4</sup> These producers, some as small as A&P, manufacture approximately 1,000 different active ingredients, each registered with EPA.<sup>5</sup>

<sup>&</sup>lt;sup>4</sup>U.S. Environmental Protection Agency, Regulatory Impact Analysis: Data Requirements for Registering Pesticides Under the Federal Insecticide, Fungicide, and Rodenticide Act 81, 82, 86 (1982) ("Regulatory Impact Analysis").

<sup>&</sup>lt;sup>5</sup> *Id.* at 81. Approximately 35,000 different finished products have been registered. *Id.* 

These chemicals normally must be dissolved, diluted, or otherwise formulated into finished products. Approximately 3,300 firms are engaged in such formulation, including many that also manufacture the basic pesticide chemicals.

Roughly forty of the 130 producers are responsible for the research and development that both identifies potential new pesticides and tests them for safety and efficacy.\* Whether large or small, the firms that develop and register a new pesticide, referred to here as "developers," are also those that generate the data necessary to demonstrate safety.

The remaining firms that produce or formulate pesticides rely for their entry into the market on the work done by the developers. These firms can be divided into two groups: those registering products in reliance on the "formulator's exemption," and those registering products by citing data submitted by previous registrants. The great majority rely upon Section 3(c)(2)(D) of FIFRA, the formulator's exemption. To qualify for that exemption, the formulator may not manufacture the active ingredient but must purchase a registered pesticide from its developer or another producer for formulation into an end-use product, and is then exempt from citing the data

<sup>&</sup>lt;sup>6</sup>S. Rep. No. 334, 95th Cong., 1st Sess. 37 (1977).

<sup>&</sup>lt;sup>7</sup> Regulatory Impact Analysis 130-31 (1982). A Senate committee in 1977 found that there were about 400 producers of basic pesticide chemicals and about 5,300 plants engaged in pesticide formulation. S. Rep. No. 334, 95th Cong., 1st Sess. 27-28 (1977). These numbers are larger than those in the EPA study, presumably because the committee report counted plants and the EPA study counted firms.

<sup>\*</sup>S. Rep. No. 334, 95th Cong., 1st Sess. 27 (1977). A recent industry survey found 36 companies reporting some research and development activity, which suggests that the above estimate is still roughly accurate. National Agricultural Chemicals Association, 1982 Industry Profile Study 2-3 (1983).

<sup>&</sup>lt;sup>9</sup> See Regulatory Impact Analysis 130-31 (1982).

supporting the registration of the purchased product and from offering to compensate the developer. <sup>10</sup> The formulator's exemption in effect allows a developer, after arm's-length negotiations and at the outset, to sell to formulators at a price sufficient to recoup its development and registration costs. <sup>11</sup> Indeed, the rationale for the exemption was that a formulator purchasing a registered pesticide already pays some amount, included in the agreed-upon purchase price, that reflects the developer's cost of generating the registration data for that chemical. <sup>12</sup> Registrations issued pursuant to the formulator's exemption, unlike registrations issued under the provisions challenged here, thus benefit developers as well as the subsequent registrants and are not at issue in this case.

The ninety or so remaining registrants, <sup>13</sup> which are neither developers nor among the vast majority that rely on the formulator's exemption, are the small class of registrants about which this case actually is concerned. These follow-on registrants register products by relying on data submitted by prior registrants. Only this handful of companies obtains all of the economic benefits of registration without generating the necessary data or properly compensating those who do. The data compensation provisions of FIFRA do not assure developers of adequate cost recovery. Unlike the up-front,

<sup>&</sup>lt;sup>10</sup> FIFRA § 3(c)(2)(D), 7 U.S.C. § 136a(c)(2)(D). The formulator may be required to submit or cite health and safety studies on its particular end-use formulation. 40 C.F.R. § 162.9-8(a) and (b) (1983).

<sup>11</sup> See Regulatory Impact Analysis 131 (1982).

<sup>&</sup>lt;sup>12</sup> See, e.g., 123 Cong. Rec. 36000 (1977) (remarks of Rep. Foley); Extending and Amending FIFRA: Hearings Before the Subcomm. on Department Investigations, Oversight and Research of the House of Representatives Comm. on Agriculture, 95th Cong., 1st Sess. 173 (1977).

<sup>&</sup>lt;sup>13</sup> This number is based primarily on the difference between the total number of producers (approximately 130; see n.4, supra) and the number of producers who develop new pesticides (approximately 40; see n.8, supra).

voluntary, arm's-length negotiations between a developer and a formulator, a developer receiving an inadequate compensation offer from a follow-on registrant will ultimately be bound by arbitration ending years after the follow-on company is on the market. There have been only three compensation decisions under FIFRA to date, and they have awarded developers only a small fraction of the cost, and a smaller fraction of the value, of their data. See pp. 25-26, infra.

Moreover, because these follow-on registrants are not involved in generating the required safety data, they often know little about the health effects of the products they sell. See, e.g., Brief for the AFL-CIO et al. as Amici Curiae in Support of Appellant ("AFL-CIO Br.") 27-28 n.18; Brief of the American Chemical Society et al. as Amici Curiae in Support of Appellee ("ACS Br.") 13-14. Affirmance of the decision below therefore would advance health and safety protection by ensuring that pesticides enter the marketplace through companies that test and remain attentive to the effects of their products or through parties to commercial relationships with the developers, which have the major investment incentive to ensure that their purchasers properly formulate and label the products sold. See, e.g., ACS Br. at 13-14.

## B. Firms That Develop And Register New Pesticides Do So At Great Expense And Economic Risk.

For those firms, large and small, that accept the risk and expense of developing and registering new pesticides and new uses for existing pesticides, the cost has always been substantial, and is rising. Innovation requires synthesis of new compounds, screening for biological and pesticidal activity, and a gauntlet of increasingly demanding tests for safety and efficacy, including those required to support registration. <sup>14</sup> The direct costs of meeting registration requirements have

<sup>&</sup>lt;sup>14</sup> J.S. App. 5a-7a. See also National Agricultural Chemicals Association, 1982 Industry Profile Study 9 (1983).

been estimated by EPA at 1.8 to 2.8 million dollars per major crop chemical, and, by a Senate committee some years ago, at seven million dollars for a food use pesticide. These estimates may be low; SDS's costs of developing its chlorothalonil registration data, for instance, are many times EPA's estimates. Even after registration, EPA often requires additional data; SDS has been generating the test data to obtain and maintain its chlorothalonil registrations from the mid-1960's until the present, and A&P has continued to generate data on CYTEX. In addition, the development by PBI and others of new uses for a product requires substantial additional research on the product's effectiveness for the new uses and the generation of data to support registration of those uses.

Furthermore, the costs described above are only a small portion of the total research and development costs necessary to develop a new pesticide. Over 10,000 compounds are synthesized for each one that succeeds, <sup>16</sup> and the number of compounds that must be screened to yield a viable product is increasing. <sup>17</sup> Taking into account the costs of screening compounds rejected at some stage in the process, EPA has estimated the cost of bringing a new chemical to market to be between twenty and seventy million dollars. <sup>18</sup> Although all

<sup>&</sup>lt;sup>15</sup> Regulatory Impact Analysis 89 (1982); S. Rep. No. 334, 95th Cong., 1st Sess. 30 (1977).

<sup>&</sup>lt;sup>16</sup> See, e.g., Regulatory Impact Analysis 129 (1982) (89,343 compounds screened and seven conditional registrations granted for new products in 1980).

<sup>&</sup>lt;sup>17</sup> ICF, Inc., Economic Profile of the Pesticide Industry 57 (1980).

<sup>&</sup>lt;sup>18</sup> Regulatory Impact Analysis 90 (1982). The latest industry data support this estimate. In 1982, thirteen new pesticide products were registered, while the industry spent over \$346 million for new pesticide research, out of a total research and development effort of over \$526 million. National Agricultural Chemicals Association, 1982 Industry Profile Study 7, 9 (1983). Thus, over \$26 million was spent per new product registration.

these costs must be absorbed by sales of the few successful chemicals, <sup>19</sup> only a minute portion have been considered compensable pursuant to the data compensation provisions of FIFRA. <sup>20</sup>

The mandatory data licensing provisions do not work a transfer merely from large to small firms. Contrary to suggestions that mandatory licensing is necessary to permit small firms to participate in the industry, 21 small firms play a significant role in developing new products and uses. A&P and PBI are both small companies engaged in such work, and two of the seven registrations granted for new pesticides in 1980 were to small producers, with annual sales under fifteen million dollars. Therefore, small as well as large firms are substantially injured by mandatory licensing.

## C. Mandatory Licensing Transfers A Major Unearned Benefit To A Small Class Of Follow-On Registrants.

Issuance of a follow-on registration can have a major economic impact upon both the developer and the follow-on registrant. Because the follow-on registrant, unlike the developer, has not spent millions of dollars on the safety and efficacy data necessary to obtain the original registration, nor the tens of millions of dollars necessary to evaluate thousands of other compounds ultimately rejected, the follow-on registrant has a significant artificial cost advantage that may be translated into substantial windfall profits.

Thus, the mandatory licensing process transfers a major economic benefit directly from the developer to the follow-on registrant. The resulting economic injury is particularly pronounced for those developers, large and small, that depend

<sup>&</sup>lt;sup>19</sup>S. Rep. No. 334, 95th Cong., 1st Sess. 36 (1977).

<sup>20</sup> See pp. 25-26, infra.

<sup>21</sup> See PPA Br. at 3-4, 15-16.

<sup>22</sup> Regulatory Impact Analysis 128-29 (1982).

primarily on sales of one or two pesticide chemicals they have developed.<sup>23</sup> A&P and SDS are such companies: CYTEX is A&P's only product, and chlorothalonil products account for over half of SDS's sales and profits.

In sum, mandatory licensing takes the value of test data away from innovators in the pesticide field by using the data for the private benefit of a small class of follow-on registrants.

### D. Mandatory Data Licensing Is Not Necessary To Ensure Competitive Pesticide Prices.

Even in the absence of the mandatory licensing provisions, the developer of a new pesticide would be limited in the price it could charge, contrary to assertions that only those provisions prevent developers from raising their prices "with impunity." PPA Br. at 16. Competition from alternative pesticides already tends to lower prices, reducing the likelihood of a "sharp price drop" as a result of another company's marketing of the same product. A study done for EPA found an average of five competing herbicides and five different insecticides available for use on each of the major crops reviewed. Description of the major crops reviewed.

Even for the few pesticide needs that are satisfied primarily by one or a few products, the constant process of innovation leads to the replacement of dominant products and firms by new ones.<sup>25</sup> The source of such new competing products, of

<sup>&</sup>lt;sup>25</sup> See Extension of the Federal Insecticide, Fungicide, and Rodenticide Act: Hearings Before the Subcomm. on Agricultural Research and General Legislation of the Senate Comm. on Agriculture, Nutrition, and Forestry, 95th Cong., 1st Sess. 251 (1977).

<sup>&</sup>lt;sup>24</sup> EPA, Agricultural Impact Analysis of Chlorothalonil 7 (1983) ("Agricultural Impact Analysis").

<sup>&</sup>lt;sup>25</sup> ICF, Inc., Economic Profile of the Pesticide Industry, 16-20 and Exs. 1-26—1-35 (1980).

<sup>&</sup>lt;sup>28</sup> Id. at 17, 22. As EPA has found, new product discovery is one of the major routes by which competitive advantage is sought in the pesticide industry. Regulatory Impact Analysis 84 (1982).

course, is not the follow-on registrants but the companies that take the risks to invest in the development of new products—risks that companies are encouraged to take if the value of their trade secrets is protected.

The chlorothalonil example adds concrete evidence that mandatory data licensing is not necessary to ensure competitive pesticide prices. The EPA study cited in the PPA Brief at 12-13 evaluated the economic impact of cancellation of Griffin's follow-on registration, which would leave SDS as the only registrant of technical chlorothalonil. The study found that even the "worst case" possibility, a five dollar per gallon price rise, would have no significant impact on crop or food prices, largely because pesticide costs are such a small proportion of the total cost of crop production.<sup>27</sup> Moreover, EPA has recognized that such a pricing decision is the result of numerous business considerations, such as the desire to penetrate new markets by lowering prices, and does not depend solely on the presence or absence of competitors selling identical products.<sup>28</sup>

Even if the presence of different companies selling the same product is a positive influence on pricing, elimination of mandatory licensing would not destroy that influence. The argument that almost every small company would be forced off the market if the decision below is affirmed, PPA Br. at 4, is simply wrong. Those companies could generate their own data as do other registrants, including those as small as A&P. They could also rely on the formulator's exemption, as do most small companies, or they could, like PBI, obtain developers' permission to rely on previously submitted data through arm's-length

<sup>&</sup>lt;sup>27</sup> Agricultural Impact Analysis 1, 9-11 (1983); Notice of Intent to Hold a Hearing, 49 Fed. Reg. 509 (1984).

<sup>&</sup>lt;sup>28</sup> See Agricultural Impact Analysis 7-9 (1983); Notice of Intent to Hold a Hearing, 49 Fed. Reg. 510-11 (1984).

negotiations.<sup>29</sup> This is how EPA's pesticide registration program currently is operating in response to the district court's decision. See EPA P.R. Notice 83-4 as amended by P.R. Notice 83-4A (1983).

It is also how the new drug application procedures of the Food and Drug Administration ("FDA") have operated for years. In fact, the absence of a significant competitive benefit from mandatory licensing is illustrated by the preservation of competition in the pharmaceutical industry without resort to a statutory giveaway for the benefit of follow-on registrants. FDA requires applicants for approval of follow-on drugs to meet the same data requirements imposed upon manufacturers of "pioneer drugs." 21 U.S.C. § 355 (1982); 21 C.F.R. § 314.1 (1983); United States v. Generix Drug Corp., \_\_\_\_\_ U.S. \_\_\_\_\_, 103 S. Ct. 1298 (1983). Neither the statute nor the regulations allow follow-on applicants to use, or FDA to consider, data submitted by the pioneer registrant. As this Court ob-

Affirmance would not be a de facto extension of patent protection. A patent confers exclusive rights to a product for a period of time. Trade secret protection prevents use or disclosure of valuable commercial information but does not prevent another company from developing similar information on its own or from obtaining a pesticide registration to market the product to which that information relates. Patents and trade secrets create separate sets of rights, each entitled to protection. See Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470 (1974). The protection of one such set of rights has no effect on the other, as is clearly illustrated by EPA's issuance of follow-on registrations for currently patented products. In the case of chlorothalonil, for example, SDS's patents do not expire until July, 1984, yet Griffin has already obtained two registrations in reliance on SDS's data. EPA therefore is simply incorrect in asserting that the "data consideration provisions come into play when the chemical or product is not patentable or when patent protection has expired." Brief for the Appellant ("App. Br.") at 13.

<sup>&</sup>lt;sup>30</sup> Manufacturers of follow-on drugs duplicating pioneer drugs approved before 1962 may in limited circumstances be permitted to file an abbreviated new drug application and therefore to rely on data

served only last term, the subsequent applicants still enjoy a cost advantage, despite the costs of developing the necessary data on their own. *Id.* at 1299 n.1 (1983).

In short, FIFRA's transfer of a large unearned private benefit to follow-on registrants creates no significant public benefit in terms of increased competition or lower prices for agricultural products.

II. THE MANDATORY DATA LICENSING SCHEME IS AN UNCONSTITUTIONAL TAKING OF DATA SUB-MITTERS' PROPERTY FOR PRIVATE PURPOSES AND WITHOUT JUST COMPENSATION.

In light of the purposes of FIFRA and the structure of the pesticide industry set forth above, it is clear that the mandatory licensing scheme is unconstitutional.<sup>31</sup>

generated by the FDA itself through its Drug Efficacy Study Implementation. 21 C.F.R. § 314.2 (1983). Any manufacturer, including one seeking to copy a post-1962 drug, may demonstrate safety and effectiveness by relying on reports of studies in the published literature. 48 Fed. Reg. 2751, 2753 (1983).

<sup>31</sup> The discussion below focuses on the data licensing rather than disclosure provisions of FIFRA. Although SDS, PBI, and A&P agree that a mechanism for public review of EPA's decisions is appropriate and desirable, see AFL-CIO Br.; Brief of the American Association for the Advancement of Science et al. as Amici Curiae in Support of Appellant ("AAAS Br."), they share Appellee's view that the FIFRA disclosure provisions are unconstitutional. Possible alternatives include increased reliance on the FIFRA Scientific Advisory Panel, disclosure of nonconfidential summaries of data, and the use of reading rooms where persons other than competitors could review registration data. Other constitutional alternatives are available.

A. Data Submitters Have Protected Property Interests In Their Registration Data And The Mandatory Licensing Provisions Effect A Taking Of That Property.

For the reasons set forth by Monsanto, all three amici have protected property interests in their data. It is clear that the mandatory licensing scheme "takes" this property. EPA attempts to minimize the invasion of the developers' property interests by arguing that the licensing provisions affect only the competitive advantage conferred by the data and do not prevent other uses of the data. App. Br. at 36, 38; see also AFL-CIO Br. at 27. The competitive advantage, however, is the essence of the owner's interest in a trade secret: "A trade secret may consist of any . . . compilation of information which is used in one's business, and which gives him an opportunity to obtain an advantage over competitors who do not know or use it." Restatement of Torts § 757, comment b (1939).

The owner's interest in ensuring that his competitors "do not know or use" his trade secret—his "right to exclude"—is precisely the interest destroyed. The argument that the destruction of this interest is permissible because it is only one of a developer's "bundle of rights," App. Br. at 35-36; PPA Br. at 22, is contrary to this Court's holding that a taking of the right to exclude is of constitutional dimension. Kaiser Aetna v. United States, 444 U.S. at 179-80. That holding should apply

<sup>&</sup>lt;sup>32</sup> Ohio, Florida, and Missouri, where SDS, A&P, and PBI are located, all recognize and protect trade secrets as property and have adopted the Restatement of Torts § 757 definition of trade secrets. See Kewanee Oil Co. v. Bicron Corp., 416 U.S. at 474; Cincinnati Bell Foundry Co. v. Dodds, 10 Ohio Dec. Reprint 154, 154-55 (Super. Ct. 1887); Ohio Rev. Code Ann. § 1333.51 (Page 1979); Lee v. Cercoa, Inc., 433 So.2d 1 (Fla. Dist. Ct. App. 1983); Unistar Corp. v. Child, 415 So.2d 733 (Fla. Dist. Ct. App. 1982); J.S. App. 22a, 29a-31a. This Court often looks to state law as determinative of the existence of a property interest, including in taking cases. E.g., Kaiser Aetna v. United States, 444 U.S. 164, 179 (1979).

with particular force in the case of trade secrets, where the right to exclude is the entire bundle of rights.

The complete destruction of developers' property is illustrated by EPA's comment that a data submitter may avoid the licensing provisions by refraining from seeking registrations. J.S. at 16.<sup>23</sup> Since a registration is necessary to sell any pesticide product, EPA's suggested alternative would render worthless both the data and the other investments made in developing a pesticide for sale. That developers choose to seek registrations rather than to cease inventing, developing, and marketing pesticides does not mean that the unconsented use of the data on behalf of a competitor is not a taking. The developer has no choice that will assure full recovery of its investment. It may choose only between different losses of its investment.

# B. The Taking Of Data Developers' Property Is For Private Purposes And Is Therefore Unconstitutional.

Despite its traditional deference to congressional statements of purpose, the Court's resolution of taking cases ultimately depends on "ad hoc, factual inquiries" into the circumstances of each case. Kaiser Aetna v. United States, 444 U.S. at 175. Such an inquiry into the operation of mandatory licensing leads clearly to the conclusion that the taking it effects is for private purposes and is therefore unconstitutional.

<sup>&</sup>lt;sup>35</sup> Similarly, EPA has argued that developers waive their property rights when they submit the data to obtain the benefit of a registration. App. Br. at 27, 30. This argument proves too much. It is well settled that the government may not condition the granting of a benefit on the recipient's surrender of a constitutional right. Such conditions have long since been rejected by this Court as unconstitutional. See Lefkowitz v. Turley, 414 U.S. 70 (1973); Spevak v. Klein, 385 U.S. 511 (1967); Garrity v. New Jersey, 385 U.S. 493 (1967); Sherbert v. Verner, 374 U.S. 398 (1963); Speiser v. Randall, 357 U.S. 513, 526 (1958) (government may not act indirectly to "produce a result which [it] could not command directly").

#### 1. A taking for private purposes is unconstitutional.

If a taking is for private purposes, it is unconstitutional. Thompson v. Consolidated Gas Utilities Corp., 300 U.S. 55 (1937), invalidated a state administrative order limiting natural gas production. That order forced companies that had built pipelines and developed markets to purchase gas from companies that had not done so, since the production limits would have prevented the pipeline companies from selling enough gas to satisfy their markets. The companies with pipelines and markets had acquired them "at large cost." id. at 66, and the owners of other wells had "not contributed in money, services, negotiations, skill, forethought or otherwise to the development of such markets and the construction of such pipelines and other facilities," id. at 78. The Court held that "one person's property may not be taken for the benefit of another private person without a justifying public purpose, even though compensation be paid." Id. at 80.

Similarly, Pennsylvania Coal Co. v. Mahon, 260 U.S. 393 (1922), struck down a state statute prohibiting coal mining that would cause the collapse of structures belonging to parties owning only the surface rights to the land. The Court ruled this prohibition a taking of valuable property rights that the coal company had expressly reserved when it conveyed the surface rights. The Court found no "public interest sufficient to warrant so extensive a destruction" of the coal company's property. Id. at 414. As for the benefits conferred on other surface right owners who were not parties to the case, the Court did not find them adequate to establish a public purpose, reasoning that the owners had "seen fit to take the right of acquiring only surface rights, [and] we cannot see that the fact that their risk has become a danger warrants the giving to them greater rights than they bought." Id. at 416.

More recently, the Ninth Circuit invalidated the Hawaii Land Reform Act, which permitted certain lessees to acquire the land they leased by means of eminent domain. Despite the state legislature's justification of the act as a means of redressing a shortage of fee simple land and resulting inflation, the court found the taking to serve private purposes and held it unconstitutional. Midkiff v. Tom, 702 F.2d 788 (9th Cir.), prob. juris. noted sub nom. Hawaii Housing Authority v. Midkiff, \_\_\_\_ U.S. \_\_\_\_, 104 S. Ct. 334 (1983).

The hallmark of Thompson and Pennsylvania Coal is that the parties upon whom the challenged provisions conferred a benefit could have obtained that benefit themselves by investing in pipelines and market development or by purchasing more than the surface rights to the land on which they built. Under such circumstances it is impermissible for the government to transfer these benefits from parties who have made such investments to those who have not seen fit to undertake the same burdens. Yet that is exactly what FIFRA does. Companies that obtain follow-on registrations could make the investment to develop the required data, in which case their right to the benefits of a registration would be unquestioned. To give them the benefit of other companies' investments, however, is to transfer property from one private party to another and is beyond Congress' authority under the Constitution.

## 2. The private purpose of the challenged provisions is clear from their operation and effect.

The deference traditionally owed to congressional statements of purpose, e.g., Berman v. Parker, 348 U.S. 26, 32 (1954), does not end the inquiry into the purpose of a challenged statute. The determination of a statute's constitutionality is a judicial one. Congress cannot immunize a statute from judicial scrutiny merely by reciting so-called "public purposes" in the statute or its legislative history. St. Joseph Stock Yards Co. v. United States, 298 U.S. 38, 50-52 (1936).

<sup>&</sup>lt;sup>34</sup> See also United States ex rel. TVA v. Welch, 327 U.S. 546, '556-57 (Reed, J., concurring), 557-58 (Frankfurter, J., concurring) (1946); Midkiff v. Tom, 702 F.2d at 798 ("were Congress to...allow condemnation of A's private property for transfer to B, solely for B's private use, this court would necessarily find such action contrary to the fifth amendment whether or not Congress declared such proceed-

Moreover, unlike the statute at issue in Berman v. Parker, FIFRA contains no statement of its purposes. In the absence of such a statement, Appellant relies heavily on legislative history references to certain allegedly public purposes; promotion of competition and avoidance of "duplicative" testing. App. Br. at 12, 21-24. These statements, however, must be viewed in the context of FIFRA as a whole. Since its comprehensive revision in 1972, the statute has been primarily intended to regulate pesticides for the purpose of protecting health and the environment. 35 As discussed below, the limited "public purposes" claimed for mandatory licensing are inconsistent with this broader public purpose. Accordingly, because the legislative history of the statute defies attempts to characterize its purposes in a unified and consistent manner. the actual effect of the statute is the only reliable guide to its purposes. A review of the effect of mandatory licensing demonstrates that it serves private purposes.

Despite the legislative history statements that mandatory licensing was designed to promote competition, FIFRA, unlike most pro-competitive legislation, does not attempt to prohibit unfair methods of competition or to prevent unequal barriers to market entry. On the contrary, the promotion of "competition" referred to in the legislative history is simply the creation of an unfair and unequal opportunity for a narrow group of companies to avoid health and safety requirements thought to be sufficiently important to justify requiring some

ings to be for a public purpose"); Wearly v. FTC, 462 F. Supp. 589, 603 (D.N.J. 1978), vacated on other grounds, 616 F.2d 662 (3d Cir.), cert. denied, 449 U.S. 822 (1980).

<sup>&</sup>lt;sup>35</sup> See S. Rep. No. 551, 97th Cong., 2d Sess. 1 (1982); H.R. Rep. No. 566, 97th Cong., 2d Sess. 33 (1982); S. Rep. No. 334, 95th Cong., 1st Sess. 33 (1977); Staff of Subcomm. on Administrative Practice and Procedure of Senate Comm. on the Judiciary, 94th Cong., 2d Sess., The Environmental Protection Agency and the Regulation of Pesticides 3 (Comm. Print 1976); S. Rep. No. 838, 92d Cong., 2d Sess. 3 (1972); H.R. Rep. No. 511, 92d Cong., 1st Sess. 1, 4 (1971).

registrants to spend millions of dollars generating data.<sup>36</sup> This benefit is conferred merely because the follow-on companies wish neither to generate the data nor to purchase a registered active ingredient from a developer at a price that includes an element of cost recovery for the developer.

This benefit is clearly a private benefit that accrues only to these follow-on registrants. It is inconsistent with FIFRA's primary objective and, as shown above, results in little or no benefit to competition. See pp. 13-16, supra.

In the context of a health and safety statute, the suggestion that avoiding additional or "duplicative" testing somehow serves a public purpose strains credulity. There is no such thing as duplicative scientific testing. Additional testing is an important means of advancing scientific understanding, particularly since no two manufacturers use identical processes or produce identical chemicals. Contrary to the assertions in its brief, EPA has long recognized this fundamental principle:

In toxicity testing, . . . the issue often is not merely whether a pesticide causes a particular toxic effect or how toxic the pesticide is, but also how certain we are of the validity of a set of findings. If a second test of a pesticide for some toxic effect produces results which corroborate the findings of an earlier test, each set of test results gains credibility from the other. On the other hand, if the second test results are significantly different (as is not uncommon in some kinds of toxicity testing), careful review is required to attempt to explain the differences and to decide what the Agency's position should be. Thus, the more data of a given type there are for comparison, the more con-

<sup>\*\*</sup>Attempts to legitimize mandatory licensing by characterizing it as a plan to remove "unnecessary" barriers to market entry and "needless" testing, App. Br. at 12, 17, 24; PPA Br. at 12, are simply wrong. Plainly, Congress has determined that those "barriers," the data submission requirements, are necessary to protect health, safety, and the environment. The question, therefore, is whether a few companies should escape the burden of satisfying those requirements.

fident the Agency can be that its regulatory decision is sound.

44 Fed. Reg. 27945, 27946 (1979) (emphasis original). Indeed, the benefits of additional tests in preventing the problems identified by *amici* supporting EPA—failure to disclose or discover adverse effects, difficulty in interpreting controversial data, and fraudulent test results —would be substantial. Thus, nothing could be farther from the truth than to suggest that the avoidance of additional testing serves a public purpose. 40

<sup>37</sup> See also EPA's P.R. Notice 83-4 (as amended by P.R. Notice 83-4A) (1983) setting forth the interim registration procedures being followed pending this Court's decision. Those procedures require each applicant either to generate and submit all required data on its own or to obtain a previous registrant's full, advance consent to the applicant's reliance on that registrant's data. EPA notes repeatedly that if an applicant has met this requirement, the Agency may review other data in its files before determining whether the pesticide may be registered. Id. at 5, 6, 9, 20. To limit this review to one set of data. even a complete one, "would not be a scientifically sound approach to evaluating whether a pesticidally active ingredient would cause unreasonable adverse effects." Id. at 9. EPA's policy would make no sense if repeated tests of the same substance would yield only "duplicative" results. Amici do not dispute EPA's contention that the Agency should be allowed to refer to all available data, once the applicant whose product is under review has either generated all the necessary data on its own or has obtained the permission of a data submitter to rely on the latter's data.

<sup>\*</sup>See AFL-CIO Br. at 6 n.6; AAAS Br. at 4, 11-18.

<sup>\*</sup>The PPA Brief's unsupported assertions that "[t]here is no jeopardy to public health and safety" as a result of the absence of data from follow-on registrants, and that generation of such data would be "unproductive," PPA Br. at 19-20, are therefore plainly wrong.

<sup>\*\*</sup> It is equally illusory to suggest that mandatory licensing is necessary to serve the "public purpose" of preserving scarce testing resources. There is no reason to suppose that testing services would not grow to meet increased demand.

This case is not one where a statute serves public purposes and only "incidentally and gratuitously" confers private benefits, and is therefore constitutional. *Thompson* v. *Consolidated Gas Utilities Corp.*, 300 U.S. at 77. The mandatory licensing provisions are exactly the reverse: they serve private purposes with only incidental, if any, benefit to the public. They are therefore unconstitutional.

### C. Even If The Taking Were For Public Purposes, It Would Be Unconstitutional Because Data Submitters Do Not Receive Just Compensation.

Even if the Court were to find that the mandatory licensing provisions serve public purposes, they would still be unconstitutional because of the unavailability of just compensation.

FIFRA fails completely to provide for just compensation to data developers. As a threshold matter, the statute's severe limitations on judicial review of arbitration decisions ignore the cardinal principle that the determination of adequate compensation is a judicial function. Baltimore & Ohio Railroad v. United States, 298 U.S. 349, 364-69 (1936); United States v. New River Collieries Co., 262 U.S. 341, 343-44 (1923); Monongahela Navigation Co. v. United States, 148 U.S. 312, 327 (1893).

The provisions requiring follow-on registrants to offer to compensate developers for the use of their data do not result in just compensation, 41 even leaving aside the question whether any compensation from a private party can satisfy the government's obligation to compensate those from whom it takes

<sup>&</sup>lt;sup>41</sup> Neither of the other so-called "replacement rights" conferred on developers by FIFRA, App. Br. at 36, provides anything approaching just compensation. The ten-year exclusive use provision in FIF-RA, applicable only to new active ingredients, does no more than return to the data submitter part of what the statute takes away. The argument that developers may, in turn, rely on other developers' data is no more than an attempt to justify one constitutional violation by the commission of another.

property. FIFRA contains no standards that assure that compensation will be a "full and perfect equivalent for the property taken," compensating the owner not only for the property taken but also for the revenues that would have been generated by the property. Monongahela Navigation Co. v. United States, 148 U.S. at 326-29, 343; United States v. New River Collieries Co., 262 U.S. at 343. The three compensation decisions that have been issued to date have fallen far short of meeting that constitutional requirement. <sup>42</sup>

All three decisions have considered as compensable only the costs of performing tests rather than the value of the data generated. This approach undervalues the property taken. Developers' great investment in discovering and registering new products and uses, which is many times the cost solely of generating required registration data, suggests how much the value of being able to market a product can exceed the cost of the testing. Since all three decisions rejected the fair market value approach, 43 the compensation awarded was not "just" within the meaning of the Fifth Amendment. 44

Furthermore, even under the cases' approach of considering costs rather than value, some costs have been deemed noncompensable. Unrecoverable costs include costs for data sub-

<sup>42</sup> Stauffer Chemical Co. v. PPG Industries, Inc., Docket No. PPG Industries, Inc. 16-199-077-82 FIFRA (1983) (Birch, Smolka, and Vassil, Arb.) ("Stauffer"); Union Carbide v. Thompson-Hayward Chemical Co., FIFRA Comp. Docket No. 27 (1982) ("Thompson-Hayward"); Ciba-Geigy Corp. v. Farmland Industries, Inc., FIFRA Comp. Docket Nos. 33, 34, and 41 (1980) ("Farmland").

<sup>45</sup> Stauffer, slip op. at 17-18; Thompson-Hayward, slip op. at 67-69; Farmland, slip op. at 28-32.

<sup>&</sup>lt;sup>44</sup> The value of the test data in question might be more fairly estimated on the basis of the entire effort resulting in the discovery and registration of the pesticide. However, this approach also has been rejected by the three cases. Stauffer, slip op. at 17; Thompson-Hayward, slip op. at 50-51; Farmland, slip op. at 44-45.

mitted before 1970 and not cited later;<sup>45</sup> efficacy studies performed to meet the statutory requirement that a product satisfy its label claims,<sup>46</sup> but not submitted;<sup>47</sup> efficacy studies required to be submitted by the initial registrant, if submission is no longer required at the time of the follow-on registration;<sup>48</sup> and safety data determined to be "substantially duplicative of other submitted data,"<sup>49</sup> even though such tests provide additional information, and may have been performed with the reasonable belief that the data were required to ensure registration.

Another fundamental shortcoming of the decisions has been their reliance on predicted market shares, which are inherently speculative. No procedure exists for modifying an award if market shares change substantially, as they well may, given the cost advantages enjoyed by the follow-on registrants.

In light of this uneven distribution of the costs of becoming a pesticide registrant, it is clear that mandatory licensing is not merely a regulation designed to adjust "the benefits and burdens of economic life," Usery v. Turner Elkhorn Mining Co., 428 U.S. 1, 15 (1976). Rather, Congress has selected one segment of the pesticide industry to discharge, for the entire industry, the burdens of satisfying the health and safety concerns associated with the marketing and use of pesticides, and another small segment of the industry to escape sharing in those burdens. This is precisely the type of provision that is addressed by the constitutional limitations on takings of pri-

<sup>&</sup>lt;sup>45</sup> Such costs are not compensable under FIFRA § 3(c)(1)(D), 7 U.S.C. § 136a(c)(1)(D). Stauffer, slip op. at 6-7, 18.

<sup>&</sup>lt;sup>46</sup> See Proposed Data Requirements, 47 Fed. Reg. 53192, 53197, 53214 (1982) (to be codified as 40 C.F.R. Part 158).

<sup>&</sup>lt;sup>47</sup> EPA requires the actual submission of efficacy data only for products intended to control organisms posing human health threats. See 40 C.F.R. § 162.163(b)(2), 48 Fed. Reg. 34000, 34006 (1983).

<sup>48</sup> Stauffer, slip op. at 9-10.

<sup>49</sup> Id. at 18-19.

vate property: "The Fifth Amendment's guarantee . . . [is] designed to bar Government from forcing some people alone to bear public burdens which, in all fairness and justice, should be borne as a whole." Armstrong v. United States, 364 U.S. 40, 49 (1960). See also Monongahela Navigation Co. v. United States, 148 U.S. at 325. 50

The district court's decision that mandatory licensing is unconstitutional is correct and should be affirmed.

III. THE COURT NEED NOT DECIDE AT THIS TIME WHETHER A DECISION IN FAVOR OF APPELLEE MUST BE RETROACTIVELY APPLIED, AND SHOULD NOT FORECLOSE RETROACTIVE APPLICATION IN APPROPRIATE CASES.

The PPA Brief suggests that a possible consequence of affirmance of the district court's decision would be the invalidation of existing follow-on registrations. PPA Br. at 5, 14. That brief thus implicitly invites the Court to address the question whether a decision in Monsanto's favor must be applied to registrations issued prior to that decision. The Court should reject the invitation to go beyond the record in this case, which raises only the question of prospective application, until it has before it a case and a record providing a basis for the factual inquiries relevant to a decision on retroactivity.

Based on the rule that a court must apply the law in effect at the time it decides a case even if the law has changed since the case first arose, see United States v. The Schooner Peggy, 5 U.S. (1 Cranch) 103 (1801), courts have traditionally presumed that a judicial decision will be applied to pending and subsequent cases involving events prior to the decision, in unless

<sup>&</sup>lt;sup>50</sup> Amici agree with Monsanto that the Tucker Act is not available to provide compensation for the taking of developers' data.

<sup>&</sup>lt;sup>51</sup> See, e.g., Gulf Offshore Co. v. Mobil Oil Corp., 453 U.S. 473, 486 n.16 (1981); Thorpe v. Housing Authority, 393 U.S. 268, 281-82 (1969); Johnson v. Lehman, 679 F.2d 918, 920-21 (D.C. Cir. 1982); Mullins v. Andrus, 664 F.2d 297, 302-03 (D.C. Cir. 1980).

such retroactivity would create "manifest injustice." The leading decision on the analysis required to set aside the retroactivity presumption in a civil case is *Chevron Oil Co.* v. *Huson*, 404 U.S. 97 (1971). Under *Chevron*, a determination whether to limit a decision to prospective effect requires analysis of three questions:

- whether the decision establishes a new principle of law, either by overruling clear precedent on which litigants had relied, or by deciding an issue of first impression, the resolution of which was "not clearly foreshadowed";
- (2) whether retroactive application would further or retard the purpose of the decision; and
- (3) whether retroactivity would be inequitable.

#### Id. at 106-07.53

Because these three factors require careful analysis before the Court can properly foreclose retroactive relief, and because the record in this case does not provide the basis for such an analysis, this Court should refrain from addressing the question of retroactivity. Registrations issued prior to the district court's decision were approved under a wide variety of

<sup>&</sup>lt;sup>52</sup> As applied to decisions, such as that sought here, that a statute is unconstitutional, the general rule is reflected in this Court's comment that "[a]n unconstitutional act is not a law; it confers no rights; it imposes no duties; it affords no protection; it creates no office; it is, in legal contemplation, as inoperative as though it had never been passed." Norton v. Shelby County, 118 U.S. 425, 442 (1886).

<sup>&</sup>lt;sup>33</sup> "[A]ll questions of civil retroactivity continue to be governed by the standard enunciated in Chevron Oil Co. v. Huson. . ." United States v. Johnson, 457 U.S. 537, 563 (1982). Although *Chevron* involved a question of statutory interpretation, the opinion did not limit the test to such cases, and it has been applied to constitutional decisions. See, e.g., Zweibon v. Mitchell, 606 F.2d 1172 (D.C. Cir. 1979), cert. denied, 453 U.S. 912 (1981); Dasho v. Susquehanna Corp., 461 F.2d 11 (7th Cir.), cert. denied, 408 U.S. 925 (1972).

factual circumstances. Retroactivity may not be appropriate for all of these registrations, but may be justified for some.

If the Court defers consideration of retroactivity, any review of existing registrations would presumably occur only after full administrative or judicial consideration. For example. FIFRA and EPA regulations provide that a registrant must be given notice of the Agency's intent to cancel and an opportunity for a full administrative hearing. 4 Such a hearing. or an action in court, would create a record providing a full basis for review of the appropriate extent of retroactive application. For instance, the record to be generated in the proceeding on Griffin's chlorothalonil registration55 will reflect, inter alia, the effect of EPA's breach of a written agreement requiring advance notice of the use of SDS's data on behalf of another company, data compensation disputes still pending between SDS and Griffin at the time of the district court's decision, and the fact that there is not yet any Griffin chlorothalonil on the market.

Because of the wide variety of circumstances that may exist with respect to registrations issued before the decision in this case, this Court should decline to foreclose retroactive relief.

<sup>&</sup>lt;sup>34</sup> FIFRA § 6(b) and (d), 7 U.S.C. § 136d(b) and (d); 40 C.F.R. Part 164 (1983).

<sup>35</sup> See p. 2, supra.

#### CONCLUSION

The judgment of the district court should be affirmed.

Respectfully submitted,

HAROLD HIMMELMAN CYNTHIA A. LEWIS VIRGINIA S. ALBRECHT PAUL E. SHORB, III

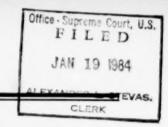
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January 19, 1984

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#### IN THE

## Supreme Court of the United States

OCTOBER TERM, 1983

WILLIAM D. RUCKELSHAUS, ADMINISTRATOR, UNITED STATES ENVIRONMENTAL PROTECTION AGENCY,

Appellant.

V.

MONSANTO COMPANY,

Appellee.

On Appeal From The United States District Court For The Eastern District Of Missouri

# BRIEF FOR STAUFFER CHEMICAL COMPANY AS AMICUS CURIAE

IN SUPPORT OF AFFIRMANCE

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## TABLE OF CONTENTS

	Page
TABLE OF AUTHORITIES	ii
INTEREST AND POSITION OF THE AMICUS	1
SUMMARY OF ARGUMENT	3
ARGUMENT	5
I. THE COURT SHOULD NOT CONSIDER WHETHER FIFRA PROVIDES A STANDARD FOR COMPENSATION	5
A. The Question Of Whether FIFRA Provides A Standard Is Not Presented, Or Is At Most A Peripheral Issue	5
B. Jurisprudence Dictates That The Court Not Consider The Question Of A FIFRA Compen- sation Standard	6
C. PPG Is Attempting To Interject A Compensation Standard Issue Into This Case	7
II. FIFRA DOES NOT ESTABLISH A STANDARD FOR COM-	
PENSATION	8
A. The Statute And Its Legislative History	8
B. The Legislative History Cited By PPG Is To Statutes Which Either No Longer Exist Or Never Were Enacted	12
C. PPG's Citations To Cost-Sharing Are Contradicted By Other Statements In FIFRA's Legislative History	13
D. PPG's Cost-Sharing Standard Is Inconsistent With Other Mandatory Licensing Schemes	15
E. PPG's Version Of Cost-Sharing Does Not Re- flect The True Costs Incurred By Pesticide In- novators	17
Conclusion	19
CONCLUSION	19

## TABLE OF AUTHORITIES

CASES:	Page
Associated Teachers of Huntington, Inc. v. Board of Education, 33 N.Y.2d 229, 306 N.E.2d 791 (1973)	11
Ciba-Geigy Corp. v. Farmland Industries, Inc., FIFRA Comp. Dkt. Nos. 33, 34 & 41 (Aug. 19, 1980)	14
Enterprise Manufacturing Co. v. Shakespeare Co., 141 F.2d 916 (6th Cir. 1944)	16
Everett v. Brown, 120 Misc. 349, 198 N.Y.S. 462 (Sup. Ct. 1923)	11
Fukaya Trading Co. v. Eastern Marine Corp., 322 F. Supp. 278 (E.D. La. 1971)	10
Golden v. Zwickler, 394 U.S. 103 (1969)	6
Marcy Lee Manufacturing Co. v. Cortley Fabrics Co., 354 F.2d 42 (2d Cir. 1965)	10
Monsanto Co. v. Acting Administrator, EPA, 564 F. Supp. 552 (E.D. Mo.), prob. juris. noted, 104 S. Ct. 230 (1983)	5
Park Construction Co. v. Independent School District No. 32, 11 N.W.2d 649 (1943)	10
PPG Industries, Inc. v. Stauffer Chemical Co., No. 83-1941 (D.D.C. filed July 7, 1983)	2, 7
Riverboat Casino, Inc. v. Local Joint Executive Board, 578 F.2d 250 (9th Cir. 1978)	10
Singer v. Flying Tiger Line Inc., 652 F.2d 1349 (9th Cir. 1981)	10
South Carolina v. Katzenbach, 383 U.S. 301 (1966)	6
Union Carbide Agricultural Products Co. v. Ruckel- shaus, 571 F. Supp. 117 (S.D.N.Y. 1983), appeal noticed Dec. 21, 1983	4 7
United States v. 564.54 Acres of Land, 441 U.S. 506	, 4, 1
(1979)	16
United States v. National Lead Co., 332 U.S. 319 (1947)	16
United States v. Raines, 362 U.S. 17 (1960)	6
University Computing Co. v. Lykes-Youngstown Corp., 504 F. 2d 518 (5th Cir. 1974)	16

## **Table of Authorities Continued**

I	age
University of Alaska v. Modern Construction, Inc., 522 P.2d 1132 (Alaska 1974)	11
Vitro Corp. of America v. Hall Chemical Co., 292 F.2d 678 (6th Cir. 1961)	16
Wilko v. Swan, 346 U.S. 427 (1953)	10
STATUTES:	
Atomic Energy Act, 42 U.S.C. § 2183 (1976)	16
Clean Air Act, 42 U.S.C. § 7608 (Supp. V 1981)	16
Federal Environmental Pesticide Control Act of 1972, Pub. L. No. 92-516, 86 Stat. 973	, 12
Federal Insecticide, Fungicide, and Rodenticide Act	
Section 3(c)(1)(D), 7 U.S.C. § 136a(c)(1)(D) (1982)	9
Section 3(c)(1)(D)(i), 7 U.S.C. § 136a(c)(1)(D)(i) (1982)	12
Section 3(c)(1)(D)(ii), 7 U.S.C. § 136a(c)(1)(D)(ii) (1982)	
Section 3(c)(2)(B), 7 U.S.C. § 136a(c)(2)(B) (1982)9	. 12
Section 3(c)(2)(B)(iii), 7 U.S.C. § 136a(c)(2)(B)(iii) (1982)	9
Section 3(c)(2)(D), 7 U.S.C. § 136a(c)(2)(D) (1982)	12
Section 3(c)(7), 7 U.S.C. § 136a(c)(7) (1982)	12
Federal Pesticide Act of 1978, Pub. L. No. 95-396, 92	12
Stat. 819	. 12
Insecticide, Fungicide and Rodenticide Act, Pub. L. No. 94-140, 89 Stat. 751 (1975)	
Plant Variety Protection Act, 7 U.S.C. § 2404 (1982)	16
Trading With The Enemy Act, 50 U.S.C. app. § 10 (1976)	16
LEGISLATIVE MATERIALS:	
H.R. Conf. Rep. No. 1540, 92d Cong., 2d Sess. (1972), reprinted in 1972 U.S. Code Cong. & Ad. News 3993	15
H.R. Rep. No. 497, 94th Cong., 1st Sess. (1975)	12
S. Rep. No. 334, 95th Cong., 1st Sess. (1977)	13

## **Table of Authorities Continued**

Pa	ige
H.R. Rep. No. 343 (Part I), 95th Cong., 1st Sess. (1977), reprinted in 1978 U.S. Code Cong. & Ad. News 1966	10
H.R. Rep. No. 663, 95th Cong., 1st Sess. (1977), re- printed in 1978 U.S. Code Cong. & Ad. News 1966	14
S. Rep. No. 551, 97th Cong., 2d Sess. (1982) 14,	15
H.R. Rep. No. 566, 97th Cong., 2d Sess. (1982)	14
MISCELLANEOUS:	
29 C.F.R. pt. 1440 (1983)	11
45 Fed. Reg. 28,105 (1980)	11
45 Fed. Reg. 55,395 (1980)	15
In re Stauffer Chemical Co. v. PPG Industries, Inc., Dkt. No. 16 199 077 82 FIFRA (Amer. Arb. Assoc. June 29, 1983)	2

### IN THE

## Supreme Court of the United States

OCTOBER TERM, 1983

No. 83-196

WILLIAM D. RUCKELSHAUS, ADMINISTRATOR, UNITED STATES ENVIRONMENTAL PROTECTION AGENCY,

Appellant.

v

MONSANTO COMPANY,

Appellee.

On Appeal From The United States District Court For The Eastern District Of Missouri

# BRIEF FOR STAUFFER CHEMICAL COMPANY AS AMICUS CURIAE

Having obtained the written consent of both parties, Stauffer Chemical Company ("Stauffer") is submitting this brief as *amicus curiae*. The brief supports the position of the appellee, Monsanto Company, regarding the constitutionality of section 3(c)(1)(D)(ii) of the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), 7 U.S.C. § 136a(c)(1)(D)(ii) (1982).

### INTEREST AND POSITION OF THE AMICUS

Stauffer has a unique and critical interest in this case. It is the only pesticide manufacturer which has initiated binding arbitration and received a compensation award under FIFRA § 3(c)(1)(D)(ii)—one of the two statutory

provisions under review. The Stauffer arbitration was conducted in the Spring of 1983,¹ and an award was rendered on June 29, 1983.² In July 1983, PPG Industries, Inc. ("PPG"), the respondent in the arbitration, contested the award by filing an action in the United States District Court for the District of Columbia. PPG Industries, Inc. v. Stauffer Chemical Co., No. 83-1941 (D.D.C. filed July 7, 1983).³ Now, PPG has submitted an amicus

PPG and Stauffer failed to agree on the amount of compensation due. Accordingly, on April 20, 1982, Stauffer initiated binding arbitration. See 29 C.F.R. pt. 1440 (1983). A panel of three arbitrators was appointed. The ensuing hearing (in which PPG advocated an award of token compensation) extended over a three-month period, included testimony from approximately twenty-five witnesses, generated a transcript of 2700 pages, and produced a voluminous documentary record. In a twenty-four page decision, the arbitrators awarded Stauffer an initial lump sum payment of \$1,465,000, plus quarterly running compensation payments based on PPG's "me-too" pesticide sales over the next ten years.

<sup>3</sup> Under the terms of the award, PPG was to have paid the initial lump sum to Stauffer by July 28, 1983. Instead, PPG filed its action seeking to vacate the award. Upon PPG's motion, the district court has ordered the arbitration award to be held in abeyance pending disposition of the action. The Government has moved to hold the action itself in abeyance, but PPG opposes that motion and has moved for summary judgment.

<sup>&</sup>lt;sup>1</sup> In re Stauffer Chemical Co. v. PPG Industries, Inc., Dkt. No. 16 199 077 82 FIFRA (Amer. Arb. Assoc. June 29, 1983).

<sup>&</sup>lt;sup>2</sup>The arbitration award represents compensation from PPG for using Stauffer's research data to obtain commercially valuable "metoo" pesticide registrations. Section 3(c)(1)(D)(ii) of FIFRA authorizes EPA to grant such me-too registrations on the basis of another company's data, but only if the me-too registrant first offers and agrees to compensate the original data submitter for use of the data. The statute provides that the amount of compensation is to be determined by the parties themselves, and if they cannot agree, through binding arbitration before private arbitrators under the auspices of the Federal Mediation and Conciliation Service ("FMCS").

brief for the purpose of interjecting into this appeal the same arguments against the award which it has raised, and which still are pending, in its district court action. Through its *amicus* brief, PPG seeks to undermine Stauffer's award by preempting the district court and short-circuiting the judicial process. Stauffer has a compelling need, therefore, to alert the Court to PPG's objectives.

In its district court action, PPG is attacking the arbitration award by alleging that the panel of three arbitrators is guilty of "misconduct" because they supposedly applied the wrong standard for compensation. PPG argues that FIFRA § 3(c)(1)(D)(ii) limits compensation to a share of certain narrow out-of-pocket testing costs. This is the very same argument to which PPG has devoted virtually its entire amicus brief.

Stauffer submits that the question of whether FIFRA provides a standard for compensation is not presented by this case, or is at most a peripheral issue which the Court should not address. The issue of whether there is a standard will be presented squarely in *Union Carbide Agricultural Products Co.* v. *Ruckelshaus*, 571 F. Supp. 117 (S.D.N.Y. 1983), appeal noticed Dec. 21, 1983. Furthermore, PPG has raised in its own district court action the contention that Congress intended "cost-sharing" to be the standard. Should the Court nevertheless choose to address the question here, Stauffer's position is that the statute does not provide a standard for compensation.

#### SUMMARY OF ARGUMENT

The question presented in this case is whether FIFRA's use of data provision, § 3(c)(1)(D)(ii), effects an unconstitutional taking of property. Both the Government and Monsanto agree that if there is a taking, the statute fails to provide, and was not intended to provide,

just compensation. As a result, the Court need not reach and should not consider the question of whether Congress provided a standard in FIFRA which affords just compensation.

PPG has filed an *amicus* brief for the purpose of interjecting the compensation standard question into this case. PPG's fundamental objective is to avoid paying compensation to Stauffer under the award rendered in the only FIFRA arbitration completed to date. PPG hopes to undermine that award by prompting the Court to acknowledge a narrow "cost-sharing" standard, which would in effect overrule the arbitrators and limit Stauffer's compensation to a nominal amount.

The Court should not address in any manner the question of a standard for compensation. Not only is the issue absent from or peripheral to this case, any comment by the Court could preempt the district court and hamstring the parties in the action filed by PPG to challenge the Stauffer award. Furthermore, the issue of whether FIFRA provides a standard for compensation will be presented squarely in Union Carbide Agricultural Products Co. v. Ruckelshaus, 571 F. Supp. 117 (S.D.N.Y. 1983), appeal noticed Dec. 21, 1983.

If the Court nevertheless should choose to consider the question, Stauffer's position is that there is no standard for compensation in FIFRA. Neither the statutory language nor the legislative history specifies a method for private arbitrators to follow in making an award. Furthermore, congressional statements contradict PPG's contention that Congress intended compensation to be limited to a share of certain out-of-pocket testing costs. Indeed, mandatory licensing schemes such as FIFRA

<sup>&</sup>lt;sup>4</sup> Stauffer is one of the plaintiffs in the Union Carbide case.

§ 3(c)(1)(D)(ii) commonly base compensation on value received, rather than on cost-sharing. Moreover, even under a cost-sharing approach, there are substantial research costs which PPG's standard fails to take into account.

#### ARGUMENT

- I. THE COURT SHOULD NOT CONSIDER WHETHER FIFRA PROVIDES A STANDARD FOR COMPENSA-TION
  - A. The Question Of Whether FIFRA Provides A Standard Is Not Presented, Or Is At Most A Peripheral Issue

Both parties in this case agree that the issue before the Court is whether FIFRA § 3(c)(1)(D)(ii) effects an unconstitutional taking of property. If there is a taking, there is no dispute as to whether the FIFRA arbitration procedure provides "just compensation." The Government admits that it does not. See Appellant's Jurisdictional Statement at 25 ("the intra-industry compensation scheme was not meant to provide Monsanto 'just compensation' within the meaning of the Fifth Amendment . . . . "); Appellant's Brief at 41 ("the statute provides some measure of compensation under the data consideration provisions . . . the Tucker Act . . . provides Monsanto the means to obtain whatever additional just compensation is due for any 'taking.' "). Neither the Government nor Monsanto contends that FIFRA provides, or was intended to provide, just compensation. As a result, the Court has no reason to decide whether there is a standard in FIFRA providing just compensation, much less what the standard is if there is one

Even if the parties disagreed about the lack of just compensation, the issue would be peripheral to this case. The district court in *Monsanto Co.* v. *Acting Administrator*, EPA, 564 F. Supp. 552 (E.D. Mo.), prob. juris.

noted, 104 S. Ct. 230 (1983), gave the question only cursory treatment as an off-shoot of its taking analysis. *Id.* at 566-67. Furthermore, the court found that FIFRA fails to provide just compensation not only because the statute is vague, but also because there is no provision for judicial review of arbitration awards. *Id.* Thus, the question of whether FIFRA provides a standard for compensation was ancillary to the district court's analysis.

# B. Jurisprudence Dictates That The Court Not Consider The Question Of A FIFRA Compensation Standard

As explained above, the issue of whether FIFRA provides a standard for compensation is absent from, or at most, peripheral to this case. Sound jurisprudence dictates, therefore, that the Court not rule on the question:

This Court, as is the case with all federal courts, "has no jurisdiction to pronounce any statute, either of a State or of the United States, void, because irreconcilable with the Constitution, except as it is called upon to adjudge the legal rights of litigants in actual controversies. In the exercise of that jurisdiction, it is bound by two rules, to which it has rigidly adhered, one, never to anticipate a question of constitutional law in advance of the necessity of deciding it; the other never to formulate a rule of constitutional law broader than is required by the precise facts to which it is to be applied." Liverpool, New York & Philadelphia S.S. Co. v. Commissioners of Emigration, 113 U.S. 33, 39, 5 S. Ct. 352, 355, 28 L. Ed. 899.

United States v. Raines, 362 U.S. 17, 21-22 (1960) (emphasis added). See also Golden v. Zwickler, 394 U.S. 103, 110 (1969) ("The constitutional question . . . must be presented in the context of a specific live grievance."); South Carolina v. Katzenbach, 383 U.S. 301, 316-17 (1966) ("At

the outset, we emphasize that only some of the many portions of the Act are properly before us. . . . Judicial review of these [other] sections must await subsequent litigation.").

The question of whether Congress intended to provide a standard for compensation will be presented to the Court in *Union Carbide Agricultural Products Co.* v. *Ruckelshaus*, 571 F. Supp. 117 (S.D.N.Y. 1983), appeal noticed Dec. 21, 1983. The same question also is pending in PPG's district court action challenging the *Stauffer* arbitration award. This question is a point of vigorous contention. Any comment by the Court, no matter how incidental, would preempt the district court and hamstring the parties currently litigating the issue. Furthermore, inasmuch as the issue already is on its way up to the Court in *Union Carbide*, the Court should await a full record and thorough briefing from the parties involved before addressing the question.

### C. PPG Is Attempting To Interject A Compensation Standard Issue Into This Case

In its amicus brief, PPG concedes "that the question of the constitutionality of the arbitration provision is not ripe for review in this case, and therefore should not be decided by the Court." PPG Amicus Brief at 2 (emphasis added). Yet, PPG's brief is devoted to the contention that the statute is constitutional only if a narrow "costsharing" standard for compensation is read into it.

Not coincidentally, this is exactly the same argument that PPG is propounding in its district court action challenging the Stauffer arbitration award. See PPG Indus-

<sup>&</sup>lt;sup>5</sup>The question of whether Congress provided a standard is inherent in PPG's contention that cost-sharing is the standard, and also is raised by Stauffer's counterclaim for declaratory judgment.

tries, Inc. v. Stauffer Chemical Co., No. 83-1941 (D.D.C. filed July 7, 1983). Thus, as an amicus curiae, PPG is attempting to bootstrap its district court argument up to the Supreme Court, and thereby preempt the district court.

#### II. FIFRA DOES NOT ESTABLISH A STANDARD FOR COMPENSATION

# A. The Statute And Its Legislative History

Compensation under FIFRA is controlled by § 3(c)(1)(D)(ii), as enacted by the Federal Pesticide Act of 1978, Pub. L. No. 95-396, 92 Stat. 819. See 7 U.S.C. § 136a(c)(1)(D)(ii) (1982). It is noteworthy that PPG in its amicus brief has started its argument with legislative history and not with the statute.

Section 3(c)(1)(D)(ii) does not specify a method for determining compensation. The statute states only that the original data submitter has "the right to compensation for the [me-too registrant's] use of the data." Under the statute, a me-too applicant must make "an offer to compensate the original data submitter." Further, "[t]he terms and amount of compensation may be fixed by agreement between the original data submitter and the applicant, or, failing such agreement, binding arbitration. . . ." The arbitrators are given complete discretion by the statute to award compensation as they deem appropriate under the facts and circumstances of each case.

<sup>&</sup>lt;sup>6</sup> Although PPG's Complaint alleges that FIFRA § 3(c)(1)(D)(ii) is unconstitutional, PPG has filed a Motion for Summary Judgment which presents the same argument set forth in its *amicus* brief. According to PPG, the only way the statute can be upheld is to dovetail onto it a provision for judicial review of arbitration awards, and to construe the statute as specifying a narrow cost-sharing standard for compensation.

To underscore the arbitrators' discretion, § 3(c)(1)(D)(ii) states that their determination "shall be final and conclusive, and no official or court . . . shall have power or jurisdiction to review any such findings and determination, except for fraud, misrepresentation, or other misconduct." 7 U.S.C. § 136a(c)(1)(D)(ii) (1982).

It is significant that the current version of FIFRA, which reflects major congressional changes enacted in 1978, is even *more* obtuse on compensation than was its immediate predecessor, the 1975 FIFRA. The 1975 (and 1972) versions of FIFRA § 3(c)(1)(D) provided that the me-too applicant must have "offered to pay reasonable compensation for producing the test data to be relied upon." Pub. L. No. 94-140, 89 Stat. 751, 755 (1975); Pub. L. No. 92-516, 86 Stat. 973, 980 (1972). Congress added even more flexibility to the statute with the 1978 provision, which pointedly omits the word "reasonable" and the phrase "for producing the test data to be relied upon." Instead, the 1978 statute merely provides "compensation for the use of the data."

During the congressional hearings which preceded enactment of the 1978 amendments to FIFRA, EPA Administrator Douglas Costle acknowledged that the

<sup>&</sup>lt;sup>7</sup>Additionally, other parts of the statute corroborate the conclusion that FIFRA § 3(c)(1)(D)(ii) does not establish a standard for compensation, much less a cost-sharing standard. Cost-sharing is expressly mentioned in § 3(c)(2)(B) of FIFRA as an optional procedure for registrants who voluntarily agree to jointly develop additional data requested by EPA on a prospective basis. See § 3(c)(2)(B)(iii), 7 U.S.C. § 136a(c)(2)(B)(iii) (1982). Section 3(c)(1)(D)(ii) provides for mandatory licensing of data previously generated by others. The fact that cost-sharing was expressly referenced in § 3(c)(2)(B), but not in § 3(c)(1)(D)(ii), supports the conclusion that Congress did not intend cost-sharing to be the standard for compensation under § 3(c)(1)(D)(ii).

statute provides no standard for compensation. He recommended that Congress establish "a uniform but equitable compensation formula" and "make more explicit what factors it [Congress] feels are pertinent in determining reasonable compensation." H.R. Rep. No. 343 (Part I), 95th Cong., 1st Sess. 8 (1977), reprinted in 1978 U.S. Code Cong. & Ad. News 1966, 1974.

Congress rejected the EPA Administrator's recommendation and declined to establish a statutory standard for compensation. Instead, Congress adopted the 1978 provision which transferred responsibility for determining compensation from EPA to private arbitrators.

The fact that Congress vested private arbitrators with the responsibility for determining compensation under § 3(c)(1)(D)(ii) is strong evidence that Congress intended not to provide a statutory standard. It is well-settled that arbitrators are expected to "fashion the law to fit the facts before them." Marcy Lee Manufacturing Co. v. Cortley Fabrics Co., 354 F.2d 42, 43 (2d Cir. 1965). Arbitrators are "expected to decide matters in dispute according to those principles of equity and good conscience which, in their opinion, will do justice between the parties." Park Construction Co. v. Independent School District No. 32. 11 N.W.2d 649, 652 (Minn, 1943), Arbitrators' decisions are not restrained by a "strait jacket of precedent," and must be made on a case-by-case basis. Singer v. Flying Tiger Line Inc., 652 F.2d 1349, 1356 (9th Cir. 1981) (citing Diamond v. Terminal Railway Alabama State Docks. 421 F.2d 228, 234 (5th Cir. 1970). See also Wilko v. Swan. 346 U.S. 427, 436 (1953); Riverboat Casino, Inc. v. Local Joint Executive Board, 578 F.2d 250, 251 (9th Cir. 1978) ("strict adherence to stare decisis would impair the flexibility of the arbitral process"); Fukaya Trading Co. v. Eastern Marine Corp., 322 F. Supp. 278, 283 (E.D. La.

1971) ("arbitrators may base their decision on principles of justice and equity"); Everett v. Brown, 120 Misc. 349, 351, 198 N.Y.S. 462 (Sup. Ct. 1923) ("[t]o require an arbitrator to follow the fixed rules of law . . . would operate to defeat the object of the proceeding. . . . [The arbitrators] are free to adopt such a course as they deem best adapted to bring about a just decision in the matters in controversy"); University of Alaska v. Modern Construction, Inc., 522 P.2d 1132, 1140 (Alaska 1974); Associated Teachers of Huntington, Inc. v. Board of Education, 33 N.Y.2d 229, 235, 306 N.E.2d 791 (1973) (arbitrator's "duty is to reach a just result regardless of the technicalities"); 5 Am. Jur. 2d Arbitration and Award § 140; 6 C.J.S. Arbitration § 60.

Further evidence of the lack of a statutory standard for compensation was provided by the Federal Mediation and Conciliation Service ("FMCS"), which FIFRA vests with the responsibility for administering data compensation arbitrations. In promulgating rules of procedure, FMCS determined that the statute does not establish a substantive standard for awarding compensation. FMCS stated:

FMCS does not propose to promulgate substantive standards for the arbitration of FIFRA disputes. Indeed, review of the statute, legislative history and background of the data compensation problem illustrates the difficulty of establishing a comprehensive set of substantive standards. The statutory scheme of FIFRA provides that the arbitrators will determine the standards on a case-by-case basis, and prior decisions may be used for guidance in further disputes.

45 Fed. Reg. 28,105, 28,107 (1980) (emphasis added). See 29 C.F.R. pt. 1440 (1983).

### B. The Legislative History Cited By PPG Is To Statutes Which Either No Longer Exist Or Never Were Enacted

In its *amicus* brief, PPG has exhaustively reviewed selected portions of FIFRA's legislative history. See PPG Amicus Brief at 6-11. It is crucially significant to note, however, that, with a single exception, all of the excerpts cited by PPG relate to pre-1978 versions of FIFRA, which are not at issue here. In the Federal Pesticide Act of 1978, Congress recast the use of data and data compensation provisions of FIFRA. Thus, the pre-1978 legislative history discussed by PPG is largely irrelevant.

<sup>\*</sup>The 1978 changes to the compensation provision were part of a major overhaul of FIFRA's registration provisions. Among the other major changes incorporated by the Federal Pesticide Act of 1978 were a new provision granting ten years of exclusive use in research data for post-1978 chemicals (§ 3(c)(1)(D)(i)); a new compensation clause providing fifteen years of compensation for both pre- and post-1978 chemicals, with disputes resolved through arbitration (§ 3(c)(1)(D)(ii)); a clause providing applicants with two optional methods of supporting their registrations: either by supplying their own test data or alternatively by citing data that had been previously submitted or that appeared in the public literature (§ 3(c)(1)(D) Preamble): an exemption of formulator-type businesses from some compensation requirements (§ 3(c)(2)(D)); a provision making trade secret research data available for mandatory licensing to imitators (§ 3(c)(1)(D)(ii)); an authorization for EPA to request additional research data from registrants after registration, with registrants having the option of developing the new studies either alone or jointly (§ 3(c)(2)(B)); and authorization for EPA to grant conditional registration of pesticides, in addition to full registration ( $\S 3(c)(7)$ ).

<sup>&</sup>lt;sup>9</sup>There are additional defects with PPG's references to the 1972 and 1975 legislative histories of FIFRA. For example, PPG has quoted an excerpt from the legislative history of the 1975 FIFRA that purports to favor cost-sharing as the basis for compensation. H.R. Rep. No. 497, 94th Cong., 1st Sess. 65 (1975). This statement is not the report of the committee and reflects nothing more than the individual opinions of the three members who expressed their dissenting or additional views.

PPG's sole reference to the legislative history of the 1978 FIFRA is to a version of the bill which never was enacted. S. Rep. No. 334, 95th Cong., 1st Sess. 4, 31 (1977). Although this report of the Senate Committee on Agriculture, Nutrition, and Forestry does mention costsharing, the bill reported by that committee was changed substantially in conference. This report is irrelevant because it does not illuminate the statute which was enacted. No cost-sharing requirement or any other standard for compensation was adopted by Congress or included in the statute.

# C. PPG's Citations To Cost-Sharing Are Contradicted By Other Statements In FIFRA's Legislative History

The legislative history of FIFRA's data compensation provision contains numerous contradictory statements. In its *amicus* brief, PPG cites several references to "costsharing," but omits the many congressional statements which are inconsistent with PPG's narrow cost-sharing standard.

PPG's standard is limited to a discrete group of out-of-pocket testing costs. This narrow cost-sharing formula does not take into account the tremendous value received by a me-too registrant who saves substantial time and money by relying upon another company's data. Nor does it take into account the level of innovation and effort that a company has put into a pesticide's development, or the need to provide incentives for pesticide research and development. The 1977 and 1982 reports of the House and Senate Agriculture Committees, however, indicate that these and similar factors are pertinent to compensation, and that compensation should be substantial, not the nominal amount which results from PPG's self-serving standard. These congressional committees stated that compensation should:

- (i) Encourage pesticide research and development. H.R. Rep. No. 663, 95th Cong., 1st Sess. 17 (1977), reprinted in 1978 U.S. Code Cong. & Ad. News 1966, 1990 ("encourage greater research for safe and effective pesticides"); id. at 18 ("assure the continued research and development of new pesticides"); S. Rep. No. 551, 97th Cong., 2d Sess. 9 (1982) ("provide effective economic incentives for companies to engage in expensive and risk-laden research programs to develop pesticides").
- (ii) Protect proprietary rights in data. S. Rep. No. 551, supra, at 9 ("protect the proprietary rights of registrants in research data"). See also H.R. Rep. No. 663, supra, at 18.
- (iii) Provide for recovery of research investments. H.R. Rep. No. 566, 97th Cong., 2d Sess. 77 (1982) (to enable the registrant "to protect and recover its investment"); S. Rep. No. 551, supra, at 13 ("providing an adequate return to data developers for the value of their research").
- (iv) Reward innovative research. S. Rep. No. 551, supra, at 9-10 ("rewarding innovative research efforts").
- (v) Make compensation more meaningful and equitable. S. Rep. No. 551, supra, at 9 ("make compensation more meaningful and equitable than under prior law").

PPG's constricted cost-sharing standard accomplishes none of the above. Taken as a whole, therefore, FIFRA's legislative history does not make a case for cost-sharing.  $^{10}$ 

<sup>&</sup>lt;sup>10</sup> PPG also relies upon the decision of an EPA administrative law judge under the pre-1978 version of the statute. Ciba-Geigy Corp. v. Farmland Industries, Inc., FIFRA Comp. Dkt. Nos. 33, 34 & 41 (Aug. 19, 1980) (see PPG Amicus Brief at 12-13). The EPA judge based compensation on cost-sharing. This was the only compensation

# D. PPG's Cost-Sharing Standard Is Inconsistent With Other Mandatory Licensing Schemes

PPG's cost-sharing standard is inconsistent with the fact that FIFRA § 3(c)(1)(D)(ii) is a mandatory licensing provision. The compensation formula advocated by PPG is based on the innovator's out-of-pocket testing costs, not on the true value received by a me-too registrant who uses the innovator's research data to obtain me-too registrations. Yet, Congress and the courts have based compensation in other mandatory licensing schemes on the value of the rights received by the licensee.

The fact that § 3(c)(1)(D)(ii) is a form of mandatory licensing cannot reasonably be disputed. FIFRA authorizes a pesticide applicant to use data "without the permission of the original data submitter." Section 3(c)(1)(D)(ii). Congress has acknowledged that the FIFRA use of data provision represents "mandatory licensing of test data." H.R. Conf. Rep. No. 1540, 92d Cong., 2d Sess. 31 (1972), reprinted in 1972 U.S. Code Cong. & Ad. News 3993, 4130. Likewise, the Federal Mediation and Conciliation Service has described the use of data provision as a "mandatory data licensing scheme." 45 Fed. Reg. 55,395 (1980).

None of the other federal statutes which establish mandatory licensing bases compensation on costs in-

case to have been decided when, in 1982, the Senate conducted oversight hearings on FIFRA's compensation provisions. The Senate Agriculture Committee's oversight report, in what had to have been a reference to the Ciba-Geigy case, stated that "data compensation has not been effective thus far." S. Rep. No. 551, supra, at 9. Thus, at least by implication, the members of the oversight committee, many of whom drafted the 1978 version of the statute, expressed dissatisfaction with cost-sharing.

<sup>11</sup> Indeed, PPG does not dispute this fact.

curred by the involuntary licensor. Instead, compensation is based on the value of the rights received by the licensee. For example, several federal statutes impose mandatory licensing of property interests in return for payment of a "reasonable royalty" to the licensor. The Atomic Energy Act, 42 U.S.C. § 2183 (1976), authorizes the mandatory licensing of patents relating to atomic energy; the Plant Variety Protection Act, 7 U.S.C. § 2404 (1982), authorizes the mandatory licensing of federally protected plant varieties; and the Trading With The Enemy Act, 50 U.S.C. app. § 10 (1976), authorizes the mandatory licensing of certain intellectual property rights during time of war. 12 In each case, the involuntary licensor is required to be compensated with a reasonable royalty for the use of the licensed property interests. 13

 $<sup>^{12}</sup>$  The Clean Air Act, 42 U.S.C. \$ 7608 (Supp. V 1981), establishes a similar scheme for the mandatory licensing of certain pollution control patents "on such reasonable terms and conditions as the court . . . may determine."

<sup>&</sup>lt;sup>13</sup> A reasonable royalty requires payment based on the value of the right that is licensed. Vitro Corp. of America v. Hall Chemical Co., 292 F.2d 678, 683 (6th Cir. 1961); Enterprise Mfg. Co. v. Shakespeare Co., 141 F.2d 916, 920 (6th Cir. 1944). Stated another way:

<sup>[</sup>A] reasonable royalty is simply that amount which the trier of facts estimates a person desiring to use a patent right would be willing to pay for its use and a patent owner desiring to license the patent would be willing to accept.

University Computing Co. v. Lykes-Youngstown Corp., 504 F.2d 518, 537 n.31 (5th Cir. 1974). See also 35 U.S.C. § 284 (1976) (patent infringement compensated by reasonable royalty for hypothetical patent license); United States v. 564.54 Acres of Land, 441 U.S. 506, 511 (1979) (compensation to be paid in eminent domain cases is to be commensurate with fair market value of right taken measured by "what a willing buyer would pay in cash to a willing seller"); United States v. National Lead Co., 332 U.S. 319, 349 (1947) (remedy for antitrust violation arising from patent misuse is involuntary license in return for reasonable royalty based upon value of rights licensed).

Thus, these other mandatory licensing schemes do not base compensation on cost-sharing. It is highly unlikely, therefore, that Congress, without explanation, would have made an exception for FIFRA and provided a cost-sharing standard for compensation.

# E. PPG's Version Of Cost-Sharing Does Not Reflect The True Costs Incurred By Pesticide Innovators

In its amicus brief, PPG argues that Congress intended to limit FIFRA compensation to a portion of the direct costs of producing test data necessary for registration. See PPG Amicus Brief at 7. Although PPG does not elaborate on what specific costs it believes are compensable, PPG's view apparently is the same narrow one that it advocated during the arbitration.

Even if Congress had intended cost-sharing to be the standard, it is unreasonable to assume that it would have limited compensable costs in the manner suggested by PPG. PPG's miserly approach to cost-sharing is to exclude all but a handful of the true costs incurred by innovators in registering a pesticide for the first time.

Pesticide innovators like Stauffer spend millions of dollars in conducting the studies and generating the many types of safety and efficacy data required for registration. These are among the regulatory research costs which innovators bear alone. Me-too registrants like PPG avoid such costs by relying upon another company's data.

Furthermore, pesticide innovators normally need five years or longer to generate government-required registration data and to undergo regulatory review before obtaining the initial registration for a new product. Because FIFRA makes it unlawful to sell a pesticide which is not registered, five or more years of sales and

profits are lost while the required data are being developed and approved. These very substantial lost profits from regulatory delays also are costs of performing government-required research. They are as real and recognizable as toxicologists' salaries and laboratory rents. Me-too registrants avoid these costs by entering the market quickly through use of another company's data.

PPG's "cost-sharing" standard excludes most out-ofpocket regulatory research costs and all costs due to regulatory delays. The result is token compensation which makes no economic sense. Congress clearly would not have intended to provide for cost-sharing by excluding the bulk of costs actually incurred by the innovator in producing the data necessary for registration.

### CONCLUSION

For the foregoing reasons, the Court should not consider the question of whether FIFRA establishes a standard for compensation. Should the Court choose to address this issue, the Court should find that Congress did not provide a standard.

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January 19, 1984

No. 83-196-AFX Title: william D. Ruckelshaus, Administrator, United States Environmental Protection Agency, Appellant Status: GRANTED Monsanto Company Docketed: August 5, 1983 United States District Court for the Court: Eastern District of Missouri Counsel for appellant: Solicitor General Counsel for appellee: Randolph Jr. A. Raymonc Proceedings and Orders Date Note Entry Application for extension of time to docket appeal and 1 Jun 30 1983 order granting same until August 8, 1983 (Blackmun, July 1, 1983). Aug 5 1983 G Statement as to jurisdiction filed. Aug 29 1983 Order extending time to file response to jurisdictional statement until September 12, 1983. Motion of appellee Monsanto Co. to affirm filed. Sep 12 1983 DISTRIBUTED. October 7, 1983 6 Sep 14 1983 Oct 4 1983 X Reply brief of appellant Ruckelshaus, Adminr., EFA filed. 7 PROBABLE JURISDICTION NOTED. Justice white OUT. 9 Oct 11 1983 \*\*\*\*\*\*\*\* 10 Nov 23 1983 Order extending time to file brief of appellant on the merits until December 2, 1983. Brief amicus curiae of PPG Industries, Inc. filec. 11 Nov 25 1983 Brief amicus curiae of Pesticide Producers Assn., et al. 12 Nov 25 1983 13 Nov 28 1983 Brief amicus curiae of American Assn. for the Advancement of Science, et al. filed. 14 Dec 2 1983 Brief amicus curiae of AFL-CIO, et al. filed. Dec 21 1983 15 arief of appellant Ruckelshaus, Adminr., EPA filed. Dec 21 1983 Joint appendix filed. 16 Dec 29 1983 18 Order extending time to file brief of appellee on the merits until January 19, 1984. 19 Dec 29 1983 Record filed. 20 Dec 29 1983 Certified original record, 3 boxes, received. Jan 9 1984 21 SET FOR ARGUMENT. Monday, February 27, 1984. (4th case) 22 Jan 18 1984 Brief amicus curiae of American Chemical Society, et al. filed. 23 Brief amicus curiae of SDS Biotech Corp., et al. filed. Jan 19 1984 Brief amicus curiae of Abbott Laboratories, et al. filed. 24 Jan 19 1984 Jan 19 1984 Brief amicus curiae of Stauffer Chemical Company filed. 25 26 Jan 19 1984 Brief of appellee Monsanto Co. filed. Jan 19 1984 Brief amicus curiae of American Patent Law Association 27 filed. 28 Jan 19 1984 Brief amicus curiae of Avco Corporation filec. Jan 20 1984 30 Brief amicus curiae of Sathon, Inc. filec. Jan 25 1984 CIRCULATED. 31 32 Feb 17 1984 X Reply brief of appellant Ruckelshaus, Adminr., EPA filed. 33 Feb 23 1984 X Supplemental brief of appellee Monsanto Cc. filed. 34 Feb 27 1984 ARGUED.